US3912163 (Prod: Synexus - Optimal Research - Austin)

US3912163

Form: Participant Creation

Data signed: (b) (4) **19 Feb 2021 16:46:59**

Generated On: 10 Jun 2021 10:19:18

Participant ID   US3912163

mRNA-1273-P301 Completion Guidelines

US3912163

Folder: Screening

Form: Visit Date

Data signed: (b) (4) **19 Feb 2021 16:47:42**

Generated On: 10 Jun 2021 10:19:18

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	15 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	SCRN

US3912163

Folder: Screening

Form: Demographics

Data signed: (b) (4) **19 Feb 2021 16:47:42**

Generated On: 10 Jun 2021 10:19:18

Date of Birth (MMM yyyy)	(b) (6) 1977
Age	43
Age Units	YEARS
Age (Derived)	43
Sex	Female ◯
	Male ⬤
Ethnicity	Hispanic or Latino ◯
	Not Hispanic or Latino ⬤
	Not Reported ◯
	Unknown ◯

Race (Check All That Apply)	
White	False
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	True
If race is Other, specify	ARABIC
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4)   **19 Feb 2021 16:47:42**

Generated On: 10 Jun 2021 10:19:18

Date of Informed Consent *(dd MMM yyyy)*	15 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020

Protocol Version

- Amendment 1 ◯
- Amendment 2 ◯
- Amendment 3 ⬤
- Amendment 4 ◯
- Amendment 5 ◯

Was participant enrolled in the study?

- Yes ⬤
- No ◯

If No, indicate reason for screen fail

- Withdrew Consent ◯
- Inclusion/Exclusion ◯
- Cohort Full ◯
- Other ◯

If reason for screen fail is Other, specify _____

Was this participant screened previously?

- Yes ◯
- No ⬤

If Yes, previous participant number _____

Enrollment Trigger	1

US3912163

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) **19 Feb 2021 16:47:42**

Generated On: 10 Jun 2021 10:19:18

Did the participant meet all eligibility criteria?   Yes ⬤

                                                             No ◯

Were any significant conditions reported?   Yes ●

                                                      No ◯

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) **19 Feb 2021 16:47:42**

Generated On: 10 Jun 2021 10:19:18

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN SEP 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) **19 Feb 2021 16:47:42**

Generated On: 10 Jun 2021 10:19:18

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	15 SEP 2020
Time of assessment *(00:00-23:59)*	10:16 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 10:16
Height *(xxx.x)*	71.5 in
Weight *(xxx.x)*	264 lb
BMI *(xxx.x)*	36.38327 kg/m^2
BMI units	KG/M2
Temperature *(xxx.x)*	ND - Not Done
Route of measurement	Oral ○
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	ND - Not Done
Pulse units	BPM
Respiratory Rate *(xxx)*	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) **19 Feb 2021 16:47:42**

Generated On: 10 Jun 2021 10:19:18

Was the physical examination performed?

Yes ●

No ○

Date of examination *(dd MMM yyyy)* 15 SEP 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 16:47:42

Generated On: 10 Jun 2021 10:19:18

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes	◯
	No	⬤
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes	◯
	No	⬤
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes	◯
	No	⬤
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes	◯
	No	⬤
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes	◯
	No	⬤
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes	◯
	No	⬤
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes	◯
	No	⬤
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes	◯
	No	⬤
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes	◯
	No	⬤
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes	◯
	No	⬤
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes	⬤
	No	◯
Other	Yes	◯
	No	⬤

Specify _____

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False

US3912163
Folder: Screening
Form: Risk of Exposure
Data signed: ▨ (b) (4) ▨ **19 Feb 2021 16:47:42**
Generated On: 10 Jun 2021 10:19:18

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	True
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

US3912163
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **19 Feb 2021 16:47:42**
Generated On: 10 Jun 2021 10:19:18

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	15 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) **19 Feb 2021 16:47:42**

Generated On: 10 Jun 2021 10:19:18

What was the date of randomization? *(dd MMM yyyy)*	15 SEP 2020
What was the participant's randomization number?	113655

In what Cohort was the participant enrolled?

- ● >=18 and <65 years and not at risk
- ○ >=18 and <65 years and at risk
- ○ >=65 years

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)	Yes ○	No ●
Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)	Yes ○	No ●
Severe obesity (body mass index > or = 40kg/m2)	Yes ○	No ●
Diabetes (Type I, Type 2, or gestational)	Yes ○	No ●
Liver Disease	Yes ○	No ●
Human Immunodeficiency Virus (HIV) infection	Yes ○	No ●

US3912163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **19 Feb 2021 16:47:42**
Generated On: 10 Jun 2021 10:19:18

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **19 Feb 2021 16:47:42**

Generated On: 10 Jun 2021 10:19:18

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	15 SEP 2020
Time of assessment *(00:00-23:59)*	10:16 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 10:16
Temperature *(xxx.x)*	37.0 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	60 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **19 Feb 2021 16:47:42**

Generated On: 10 Jun 2021 10:19:18

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	15 SEP 2020
Time of assessment *(00:00-23:59)*	12:17 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 12:17
Temperature *(xxx.x)*	37.1 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	63 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	81 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) **19 Feb 2021 16:47:42**

Generated On: 10 Jun 2021 10:19:18

Was the physical examination performed?   Yes ◯

                                                                                                    No ⬤

Date of examination *(dd MMM yyyy)* _____

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

Was study treatment given?	Yes ●
	No ○

If No, reason not given	
	Participant declined due to Adverse Event ○
	Physician withheld dose due to Adverse Event ○
	Death ○
	Lost To Follow-Up ○
	Physician Decision ○
	Pregnancy ○
	Protocol Deviation ○
	Study Terminated by Sponsor ○
	Withdrawal of Consent by Participant ○
	Confirmed COVID-19 ○
	Other ○

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? *(dd MMM yyyy)*	15 SEP 2020
What was the treatment time? *(00:00-23:59)*	11:38 (24 HR)
Treatment Date and Time (derived)	15 SEP 2020 11:38
Which arm was used to give treatment?	Left Arm ●
	Right Arm ○
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) **19 Feb 2021 16:47:42**

Generated On: 10 Jun 2021 10:19:18

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	15 SEP 2020
Collection time *(00:00-23:59)*	11:20 (24 HR)
Collection date and time (derived)	15 SEP 2020 11:20

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **19 Feb 2021 16:47:42**

Generated On: 10 Jun 2021 10:19:18

Collection date *(dd MMM yyyy)*			15 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:27	15 SEP 2020 11:27
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) **19 Feb 2021 16:47:42**

Generated On: 10 Jun 2021 10:19:18

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?	Yes ● No ○
Please record your **TEMPERATURE in °F**	98.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○ No ●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	15 SEP 2020 12:19
PC Open Date & Time	15 SEP 2020 11:58
PC Close Date & Time	15 SEP 2020 14:28

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	15 SEP 2020 15:25
PC Open Date & Time	15 SEP 2020 15:23
PC Close Date & Time	16 SEP 2020 11:59

US3912163

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 2

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	99.0 °F

Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	16 SEP 2020 12:01
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3912163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 3

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	17 SEP 2020 12:32
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3912163

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 4

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	18 SEP 2020 12:20
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3912163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 5

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?	Yes	●
	No	○
Please record your **TEMPERATURE in °F**		98.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes	○
	No	●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	19 SEP 2020 12:06
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

TIMEPOINT DAY 6

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	20 SEP 2020 12:01
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

FDA-CBER-2022-1614-3508187

US3912163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 7

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	21 SEP 2020 12:00
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3912163

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)

Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯

Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯

PC Time Stamp	15 SEP 2020 12:20
PC Open Date & Time	15 SEP 2020 11:58
PC Close Date & Time	15 SEP 2020 14:28

FDA-CBER-2022-1614-3508189

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	15 SEP 2020 15:26
PC Open Date & Time	15 SEP 2020 15:23
PC Close Date & Time	16 SEP 2020 11:59

US3912163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	16 SEP 2020 12:01
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

TIMEPOINT	DAY 3

Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○

Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○

PC Time Stamp	17 SEP 2020 12:32
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3912163

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 4
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	18 SEP 2020 12:20
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3912163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 5
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	19 SEP 2020 12:06
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

TIMEPOINT	DAY 6
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	20 SEP 2020 12:01
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3912163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 7
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	21 SEP 2020 12:01
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)

HEADACHE

None	⬤
No interference with activity	◯
Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity	◯
Any use of prescription pain reliever or prevents daily activity	◯

FATIGUE

None	⬤
No interference with activity	◯
Some interference with activity	◯
Significant; prevents daily activity	◯

MUSCLE ACHES ALL OVER BODY

None	⬤
No interference with activity	◯
Some interference with activity	◯
Significant; prevents daily activity	◯

JOINT ACHES IN SEVERAL JOINTS

None	⬤
No interference with activity	◯
Some interference with activity	◯
Significant; prevents daily activity	◯

NAUSEA/VOMITING

None	⬤
No interference with activity or 1-2 episodes/24 hours	◯
Some interference with activity or >2 episodes/24 hours	◯
Prevents daily activity, requires outpatient IV hydration	◯

CHILLS

None	⬤
No interference with activity	◯
Some interference with activity not requiring medical attention	◯
Prevents daily activity and requires medical attention	◯

FDA-CBER-2022-1614-3508197

US3912163

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:18

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	15 SEP 2020 12:21
PC Open Date & Time	15 SEP 2020 11:58
PC Close Date & Time	15 SEP 2020 14:28

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
HEADACHE	None ●
	No interference with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
FATIGUE	None ○
	No interference with activity ●
	Some interference with activity ○
	Significant; prevents daily activity ○
MUSCLE ACHES ALL OVER BODY	None ●
	No interference with activity ○
	Some interference with activity ○
	Significant; prevents daily activity ○
JOINT ACHES IN SEVERAL JOINTS	None ●
	No interference with activity ○
	Some interference with activity ○
	Significant; prevents daily activity ○
NAUSEA/VOMITING	None ●
	No interference with activity or 1-2 episodes/24 hours ○
	Some interference with activity or >2 episodes/24 hours ○
	Prevents daily activity, requires outpatient IV hydration ○
CHILLS	None ●
	No interference with activity ○
	Some interference with activity not requiring medical attention ○
	Prevents daily activity and requires medical attention ○

US3912163

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:18

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	15 SEP 2020 15:27
PC Open Date & Time	15 SEP 2020 15:23
PC Close Date & Time	16 SEP 2020 11:59

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 2

HEADACHE

- None ⚪
- No interference with activity ⚫
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ⚪
- Any use of prescription pain reliever or prevents daily activity ⚪

FATIGUE

- None ⚪
- No interference with activity ⚫
- Some interference with activity ⚪
- Significant; prevents daily activity ⚪

MUSCLE ACHES ALL OVER BODY

- None ⚫
- No interference with activity ⚪
- Some interference with activity ⚪
- Significant; prevents daily activity ⚪

JOINT ACHES IN SEVERAL JOINTS

- None ⚫
- No interference with activity ⚪
- Some interference with activity ⚪
- Significant; prevents daily activity ⚪

NAUSEA/VOMITING

- None ⚫
- No interference with activity or 1-2 episodes/24 hours ⚪
- Some interference with activity or >2 episodes/24 hours ⚪
- Prevents daily activity, requires outpatient IV hydration ⚪

CHILLS

- None ⚪
- No interference with activity ⚫
- Some interference with activity not requiring medical attention ⚪
- Prevents daily activity and requires medical attention ⚪

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? — No ⚫

	Yes ◯
PC Time stamp	16 SEP 2020 12:02
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

TIMEPOINT	DAY 3

HEADACHE

None	●
No interference with activity	○
Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity	○
Any use of prescription pain reliever or prevents daily activity	○

FATIGUE

None	○
No interference with activity	●
Some interference with activity	○
Significant; prevents daily activity	○

MUSCLE ACHES ALL OVER BODY

None	●
No interference with activity	○
Some interference with activity	○
Significant; prevents daily activity	○

JOINT ACHES IN SEVERAL JOINTS

None	●
No interference with activity	○
Some interference with activity	○
Significant; prevents daily activity	○

NAUSEA/VOMITING

None	●
No interference with activity or 1-2 episodes/24 hours	○
Some interference with activity or >2 episodes/24 hours	○
Prevents daily activity, requires outpatient IV hydration	○

CHILLS

None	●
No interference with activity	○
Some interference with activity not requiring medical attention	○
Prevents daily activity and requires medical attention	○

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ●

FDA-CBER-2022-1614-3508203

	Yes ◯
PC Time stamp	17 SEP 2020 12:33
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 4

HEADACHE
- None ⬤
- No interference with activity ◯
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ◯
- Any use of prescription pain reliever or prevents daily activity ◯

FATIGUE
- None ⬤
- No interference with activity ◯
- Some interference with activity ◯
- Significant; prevents daily activity ◯

MUSCLE ACHES ALL OVER BODY
- None ⬤
- No interference with activity ◯
- Some interference with activity ◯
- Significant; prevents daily activity ◯

JOINT ACHES IN SEVERAL JOINTS
- None ⬤
- No interference with activity ◯
- Some interference with activity ◯
- Significant; prevents daily activity ◯

NAUSEA/VOMITING
- None ⬤
- No interference with activity or 1-2 episodes/24 hours ◯
- Some interference with activity or >2 episodes/24 hours ◯
- Prevents daily activity, requires outpatient IV hydration ◯

CHILLS
- None ⬤
- No interference with activity ◯
- Some interference with activity not requiring medical attention ◯
- Prevents daily activity and requires medical attention ◯

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? — No ⬤

	Yes ◯
PC Time stamp	18 SEP 2020 12:20
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 5

HEADACHE

- None ●
- No interference with activity ○
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ○
- Any use of prescription pain reliever or prevents daily activity ○

FATIGUE

- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

MUSCLE ACHES ALL OVER BODY

- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

JOINT ACHES IN SEVERAL JOINTS

- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

NAUSEA/VOMITING

- None ●
- No interference with activity or 1-2 episodes/24 hours ○
- Some interference with activity or >2 episodes/24 hours ○
- Prevents daily activity, requires outpatient IV hydration ○

CHILLS

- None ●
- No interference with activity ○
- Some interference with activity not requiring medical attention ○
- Prevents daily activity and requires medical attention ○

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? — No ●

FDA-CBER-2022-1614-3508207

	Yes ⭘
PC Time stamp	19 SEP 2020 12:06
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 6

HEADACHE
- None ⚪
- No interference with activity ⚫
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ⚪
- Any use of prescription pain reliever or prevents daily activity ⚪

FATIGUE
- None ⚫
- No interference with activity ⚪
- Some interference with activity ⚪
- Significant; prevents daily activity ⚪

MUSCLE ACHES ALL OVER BODY
- None ⚫
- No interference with activity ⚪
- Some interference with activity ⚪
- Significant; prevents daily activity ⚪

JOINT ACHES IN SEVERAL JOINTS
- None ⚫
- No interference with activity ⚪
- Some interference with activity ⚪
- Significant; prevents daily activity ⚪

NAUSEA/VOMITING
- None ⚫
- No interference with activity or 1-2 episodes/24 hours ⚪
- Some interference with activity or >2 episodes/24 hours ⚪
- Prevents daily activity, requires outpatient IV hydration ⚪

CHILLS
- None ⚫
- No interference with activity ⚪
- Some interference with activity not requiring medical attention ⚪
- Prevents daily activity and requires medical attention ⚪

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? — No ⚫

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:19:18

	Yes ◯
PC Time stamp	20 SEP 2020 12:02
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 7

HEADACHE
- None ●
- No interference with activity ○
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ○
- Any use of prescription pain reliever or prevents daily activity ○

FATIGUE
- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

MUSCLE ACHES ALL OVER BODY
- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

JOINT ACHES IN SEVERAL JOINTS
- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

NAUSEA/VOMITING
- None ●
- No interference with activity or 1-2 episodes/24 hours ○
- Some interference with activity or >2 episodes/24 hours ○
- Prevents daily activity, requires outpatient IV hydration ○

CHILLS
- None ●
- No interference with activity ○
- Some interference with activity not requiring medical attention ○
- Prevents daily activity and requires medical attention ○

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? — No ●

	Yes ◯
PC Time stamp	21 SEP 2020 12:01
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3912163

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) **19 Feb 2021 16:47:42**

Generated On: 10 Jun 2021 10:19:18

Was Contact Attempted?	Yes ⬤
	No ◯

Date of Contact or Contact Attempt *(dd MMM yyyy)*	22 SEP 2020
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3912163

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) **19 Feb 2021 16:47:42**

Generated On: 10 Jun 2021 10:19:18

Is the participant continuing to the next visit?
Yes ⬤
No ◯

Continuing Flag
1

US3912163
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **19 Feb 2021 16:47:42**
Generated On: 10 Jun 2021 10:19:18

| Was Contact Attempted? | Yes ● |
| | No ○ |

Date of Contact or Contact Attempt *(dd MMM yyyy)*	30 SEP 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3912163

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) **19 Feb 2021 16:47:42**

Generated On: 10 Jun 2021 10:19:18

Is the participant continuing to the next visit?   Yes ⬤

    No ◯

Continuing Flag   1

US3912163
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4)   **19 Feb 2021 16:47:42**
Generated On: 10 Jun 2021 10:19:18

Was Contact Attempted?	Yes ◯
	No ⬤

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Please select one status for the follow-up contact	Contact Made ◯
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

SAFETY CALL NOT
ATTEMPTED DUE TO SITE
ERROR.

US3912163

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) **19 Feb 2021 16:47:42**

Generated On: 10 Jun 2021 10:19:18

Is the participant continuing to the next visit?　　　　　　　　　　　Yes ⬤

No ◯

Continuing Flag　　　　　　　　　　　　　　　　　　　　　　　　　1

US3912163
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **19 Feb 2021 16:47:42**
Generated On: 10 Jun 2021 10:19:18

| Was this visit performed? | Yes ⬤ |
| | No ⭘ |

Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ⭘
	Clinic ⬤

| Folder OID | VISIT2 |

US3912163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **19 Feb 2021 16:47:42**

Generated On: 10 Jun 2021 10:19:18

Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	13 OCT 2020
Time of assessment *(00:00-23:59)*	09:55 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 09:55
Temperature *(xxx.x)*	37.0 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	66 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	157 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	119 mmHg
Diastolic Blood Pressure units	MMHG

US3912163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **19 Feb 2021 16:47:42**

Generated On: 10 Jun 2021 10:19:18

Timepoint	Pre-Dose ⭕
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ⭕
Date of assessment *(dd MMM yyyy)*	13 OCT 2020
Time of assessment *(00:00-23:59)*	11:54 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 11:54
Temperature *(xxx.x)*	35.9 C
Route of measurement	Oral ⬤
	Axillary ⭕
	Other ⭕
If Other, specify	
Pulse *(xxx)*	57 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	88 mmHg
Diastolic Blood Pressure units	MMHG

US3912163

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) **19 Feb 2021 16:47:42**

Generated On: 10 Jun 2021 10:19:18

Was the physical examination performed?   Yes ⬤

                                                                              No ◯

Date of examination *(dd MMM yyyy)*   13 OCT 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

Was study treatment given?   Yes ●

                                                                              No ○

If No, reason not given   Participant declined due to ○
                                                         Adverse Event

                                                Physician withheld dose due to ○
                                                         Adverse Event

                                                                    Death ○

                                                         Lost To Follow-Up ○

                                                         Physician Decision ○

                                                                Pregnancy ○

                                                         Protocol Deviation ○

                                                Study Terminated by Sponsor ○

                                                   Withdrawal of Consent by ○
                                                            Participant

                                                        Confirmed COVID-19 ○

                                                                    Other ○

If reason is Physician Decision, Withdrawal of Consent by
Participant, Protocol Deviation, or Other, specify

What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? *(dd MMM yyyy)*	13 OCT 2020
What was the treatment time? *(00:00-23:59)*	11:11 (24 HR)
Treatment Date and Time (derived)	13 OCT 2020 11:11
Which arm was used to give treatment?	Left Arm ●
	Right Arm ○
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3912163

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **19 Feb 2021 16:47:42**

Generated On: 10 Jun 2021 10:19:18

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	13 OCT 2020
Collection time *(00:00-23:59)*	10:47 (24 HR)
Collection date and time (derived)	13 OCT 2020 10:47

US3912163

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **19 Feb 2021 16:47:42**

Generated On: 10 Jun 2021 10:19:18

Collection date (dd MMM yyyy)			13 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:53	13 OCT 2020 10:53
Nasopharyngeal Swab 2	No		

US3912163
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **19 Feb 2021 16:47:42**
Generated On: 10 Jun 2021 10:19:18

Is the participant continuing to the next visit?   Yes ●

                                                                      No ○

Continuing Flag   1

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	96.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	13 OCT 2020 11:58
PC Open Date & Time	13 OCT 2020 11:31
PC Close Date & Time	13 OCT 2020 14:01

FDA-CBER-2022-1614-3508227

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	13 OCT 2020 21:16
PC Open Date & Time	13 OCT 2020 14:56
PC Close Date & Time	14 OCT 2020 11:59

US3912163

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 2

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	14 OCT 2020 12:15
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3912163

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 3

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	97.6 °F

Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	16 OCT 2020 07:23
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3912163

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 4

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	97.8 °F

Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	16 OCT 2020 13:08
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

FDA-CBER-2022-1614-3508231

US3912163

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 5

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	97.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	17 OCT 2020 12:01
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 6

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	18 OCT 2020 12:26
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 7

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

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Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	19 OCT 2020 12:12
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ● Does not interfere with activity ○ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○ Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○ No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○ No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ● Does not interfere with activity ○ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○ Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	13 OCT 2020 11:58
PC Open Date & Time	13 OCT 2020 11:31
PC Close Date & Time	13 OCT 2020 14:01

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	13 OCT 2020 21:16
PC Open Date & Time	13 OCT 2020 14:56
PC Close Date & Time	14 OCT 2020 11:59

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	14 OCT 2020 12:16
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3912163

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 3

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

- None ●
- Does not interfere with activity ○
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
- Any use of prescription pain reliever or prevents daily activity ○

Is there any **REDNESS AT INJECTION SITE**?

- Yes ○
- No ●

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

- Yes ○
- No ●

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

- None ●
- Does not interfere with activity ○
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
- Any use of prescription pain reliever or prevents daily activity ○

PC Time Stamp	16 OCT 2020 07:24
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

TIMEPOINT	DAY 4

Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯

Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯

PC Time Stamp	16 OCT 2020 13:08
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 5

Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○

Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○

PC Time Stamp	17 OCT 2020 12:01
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

TIMEPOINT	DAY 6

Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○

Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○

PC Time Stamp	18 OCT 2020 12:27
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

TIMEPOINT	DAY 7
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	19 OCT 2020 12:13
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
HEADACHE	None ⬤
	No interference with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
FATIGUE	None ⬤
	No interference with activity ◯
	Some interference with activity ◯
	Significant; prevents daily activity ◯
MUSCLE ACHES ALL OVER BODY	None ⬤
	No interference with activity ◯
	Some interference with activity ◯
	Significant; prevents daily activity ◯
JOINT ACHES IN SEVERAL JOINTS	None ⬤
	No interference with activity ◯
	Some interference with activity ◯
	Significant; prevents daily activity ◯
NAUSEA/VOMITING	None ⬤
	No interference with activity or 1-2 episodes/24 hours ◯
	Some interference with activity or >2 episodes/24 hours ◯
	Prevents daily activity, requires outpatient IV hydration ◯
CHILLS	None ⬤
	No interference with activity ◯
	Some interference with activity not requiring medical attention ◯
	Prevents daily activity and requires medical attention ◯

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤
	Yes ◯

PC Time stamp	13 OCT 2020 11:59
PC Open Date & Time	13 OCT 2020 11:31
PC Close Date & Time	13 OCT 2020 14:01

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

HEADACHE

None	⬤
No interference with activity	◯
Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity	◯
Any use of prescription pain reliever or prevents daily activity	◯

FATIGUE

None	◯
No interference with activity	⬤
Some interference with activity	◯
Significant; prevents daily activity	◯

MUSCLE ACHES ALL OVER BODY

None	⬤
No interference with activity	◯
Some interference with activity	◯
Significant; prevents daily activity	◯

JOINT ACHES IN SEVERAL JOINTS

None	⬤
No interference with activity	◯
Some interference with activity	◯
Significant; prevents daily activity	◯

NAUSEA/VOMITING

None	⬤
No interference with activity or 1-2 episodes/24 hours	◯
Some interference with activity or >2 episodes/24 hours	◯
Prevents daily activity, requires outpatient IV hydration	◯

CHILLS

None	⬤
No interference with activity	◯
Some interference with activity not requiring medical attention	◯
Prevents daily activity and requires medical attention	◯

US3912163

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:18

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ●
	Yes ○

PC Time stamp	13 OCT 2020 21:17
PC Open Date & Time	13 OCT 2020 14:56
PC Close Date & Time	14 OCT 2020 11:59

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 2
HEADACHE	None ●
	No interference with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
FATIGUE	None ●
	No interference with activity ○
	Some interference with activity ○
	Significant; prevents daily activity ○
MUSCLE ACHES ALL OVER BODY	None ●
	No interference with activity ○
	Some interference with activity ○
	Significant; prevents daily activity ○
JOINT ACHES IN SEVERAL JOINTS	None ●
	No interference with activity ○
	Some interference with activity ○
	Significant; prevents daily activity ○
NAUSEA/VOMITING	None ●
	No interference with activity or 1-2 episodes/24 hours ○
	Some interference with activity or >2 episodes/24 hours ○
	Prevents daily activity, requires outpatient IV hydration ○
CHILLS	None ●
	No interference with activity ○
	Some interference with activity not requiring medical attention ○
	Prevents daily activity and requires medical attention ○
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ●

	Yes ◯
PC Time stamp	14 OCT 2020 12:16
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 3
HEADACHE	None ●
	No interference with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
FATIGUE	None ●
	No interference with activity ○
	Some interference with activity ○
	Significant; prevents daily activity ○
MUSCLE ACHES ALL OVER BODY	None ●
	No interference with activity ○
	Some interference with activity ○
	Significant; prevents daily activity ○
JOINT ACHES IN SEVERAL JOINTS	None ●
	No interference with activity ○
	Some interference with activity ○
	Significant; prevents daily activity ○
NAUSEA/VOMITING	None ●
	No interference with activity or 1-2 episodes/24 hours ○
	Some interference with activity or >2 episodes/24 hours ○
	Prevents daily activity, requires outpatient IV hydration ○
CHILLS	None ●
	No interference with activity ○
	Some interference with activity not requiring medical attention ○
	Prevents daily activity and requires medical attention ○
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ●

FDA-CBER-2022-1614-3508249

	Yes ◯
PC Time stamp	16 OCT 2020 07:24
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 4

HEADACHE

- None ●
- No interference with activity ○
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ○
- Any use of prescription pain reliever or prevents daily activity ○

FATIGUE

- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

MUSCLE ACHES ALL OVER BODY

- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

JOINT ACHES IN SEVERAL JOINTS

- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

NAUSEA/VOMITING

- None ●
- No interference with activity or 1-2 episodes/24 hours ○
- Some interference with activity or >2 episodes/24 hours ○
- Prevents daily activity, requires outpatient IV hydration ○

CHILLS

- None ●
- No interference with activity ○
- Some interference with activity not requiring medical attention ○
- Prevents daily activity and requires medical attention ○

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?　　　No ●

	Yes ◯
PC Time stamp	16 OCT 2020 13:09
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 5

HEADACHE

None	●
No interference with activity	○
Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity	○
Any use of prescription pain reliever or prevents daily activity	○

FATIGUE

None	●
No interference with activity	○
Some interference with activity	○
Significant; prevents daily activity	○

MUSCLE ACHES ALL OVER BODY

None	●
No interference with activity	○
Some interference with activity	○
Significant; prevents daily activity	○

JOINT ACHES IN SEVERAL JOINTS

None	●
No interference with activity	○
Some interference with activity	○
Significant; prevents daily activity	○

NAUSEA/VOMITING

None	●
No interference with activity or 1-2 episodes/24 hours	○
Some interference with activity or >2 episodes/24 hours	○
Prevents daily activity, requires outpatient IV hydration	○

CHILLS

None	●
No interference with activity	○
Some interference with activity not requiring medical attention	○
Prevents daily activity and requires medical attention	○

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ●

	Yes ◯
PC Time stamp	17 OCT 2020 12:01
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 6

HEADACHE
- None ●
- No interference with activity ○
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ○
- Any use of prescription pain reliever or prevents daily activity ○

FATIGUE
- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

MUSCLE ACHES ALL OVER BODY
- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

JOINT ACHES IN SEVERAL JOINTS
- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

NAUSEA/VOMITING
- None ●
- No interference with activity or 1-2 episodes/24 hours ○
- Some interference with activity or >2 episodes/24 hours ○
- Prevents daily activity, requires outpatient IV hydration ○

CHILLS
- None ●
- No interference with activity ○
- Some interference with activity not requiring medical attention ○
- Prevents daily activity and requires medical attention ○

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? — No ●

	Yes ◯
PC Time stamp	18 OCT 2020 12:27
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 7

HEADACHE
- None ⬤
- No interference with activity ◯
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ◯
- Any use of prescription pain reliever or prevents daily activity ◯

FATIGUE
- None ⬤
- No interference with activity ◯
- Some interference with activity ◯
- Significant; prevents daily activity ◯

MUSCLE ACHES ALL OVER BODY
- None ⬤
- No interference with activity ◯
- Some interference with activity ◯
- Significant; prevents daily activity ◯

JOINT ACHES IN SEVERAL JOINTS
- None ⬤
- No interference with activity ◯
- Some interference with activity ◯
- Significant; prevents daily activity ◯

NAUSEA/VOMITING
- None ⬤
- No interference with activity or 1-2 episodes/24 hours ◯
- Some interference with activity or >2 episodes/24 hours ◯
- Prevents daily activity, requires outpatient IV hydration ◯

CHILLS
- None ⬤
- No interference with activity ◯
- Some interference with activity not requiring medical attention ◯
- Prevents daily activity and requires medical attention ◯

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? — No ⬤

	Yes ◯
PC Time stamp	19 OCT 2020 12:13
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3912163
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **19 Feb 2021 16:47:42**
Generated On: 10 Jun 2021 10:19:18

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	20 OCT 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3912163

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) **19 Feb 2021 16:47:42**

Generated On: 10 Jun 2021 10:19:18

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3912163

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) **19 Feb 2021 16:47:42**

Generated On: 10 Jun 2021 10:19:18

Was Contact Attempted?   Yes ●

                                                                             No ○

Date of Contact or Contact Attempt *(dd MMM yyyy)*   28 OCT 2020

Please select one status for the follow-up contact   Contact Made ●

                                                            Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3912163

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) **19 Feb 2021 16:47:42**

Generated On: 10 Jun 2021 10:19:18

Is the participant continuing to the next visit?   Yes ●

                                                                    No ○

Continuing Flag   1

US3912163
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **19 Feb 2021 16:47:42**
Generated On: 10 Jun 2021 10:19:18

Was Contact Attempted?   Yes ●

                                                          No ◯

Date of Contact or Contact Attempt *(dd MMM yyyy)*   03 NOV 2020

Please select one status for the follow-up contact   Contact Made ●

                                                          Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments   _____

US3912163

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) **19 Feb 2021 16:47:42**

Generated On: 10 Jun 2021 10:19:18

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3912163

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) **19 Feb 2021 16:47:42**

Generated On: 10 Jun 2021 10:19:18

| Was this visit performed? | Yes ◯ |
| | No ⬤ |

Visit date (dd MMM yyyy) _____

| Was visit performed at the participant's home or at the clinic? | Home ◯ |
| | Clinic ◯ |

Folder OID   VISIT3

US3912163

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) **19 Feb 2021 16:47:42**

Generated On: 10 Jun 2021 10:19:18

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3912163

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-3508267

US3912163

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	**DAY 68**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⦿ Yes ⦿
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⦿ Yes ⦿
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⦿
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⦿ Yes ⦿

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 DEC 2020 10:44:19
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ⬤
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ⬤

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C)	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬤
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Date and time of submission	11 DEC 2020 16:20:19
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 DEC 2020 14:58:39
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 DEC 2020 12:44:07
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 DEC 2020 14:23:42
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 JAN 2021 11:01:37
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 JAN 2021 00:02:07
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 JAN 2021 07:21:20
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 JAN 2021 18:41:00
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚫
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⚫ Yes ⚪
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⚫ Yes ⚪
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚫
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⚫
Date and time of submission	04 FEB 2021 07:55:26
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 FEB 2021 14:38:37
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 FEB 2021 07:46:48
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 FEB 2021 07:23:01
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 MAR 2021 17:18:57
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 MAR 2021 07:11:38
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 MAR 2021 03:10:47
Patient Cloud Open Date & Time	18 MAR 2021 00:01
Patient Cloud Close Date & Time	22 MAR 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 MAR 2021 06:45:38
Patient Cloud Open Date & Time	25 MAR 2021 00:01
Patient Cloud Close Date & Time	29 MAR 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 APR 2021 20:26:09
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 208

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭
	Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭
	Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭
	Yes ⬭

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭
	Yes ⬭

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	08 APR 2021 00:01
Patient Cloud Close Date & Time	12 APR 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 APR 2021 16:51:44
Patient Cloud Open Date & Time	15 APR 2021 00:01
Patient Cloud Close Date & Time	19 APR 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 APR 2021 01:18:14
Patient Cloud Open Date & Time	22 APR 2021 00:01
Patient Cloud Close Date & Time	26 APR 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 APR 2021 08:08:44
Patient Cloud Open Date & Time	29 APR 2021 00:01
Patient Cloud Close Date & Time	03 MAY 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	**DAY 236**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	06 MAY 2021 00:01
Patient Cloud Close Date & Time	10 MAY 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	**DAY 243**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	13 MAY 2021 00:01
Patient Cloud Close Date & Time	17 MAY 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 250

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	20 MAY 2021 00:01
Patient Cloud Close Date & Time	24 MAY 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT DAY 257

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

FDA-CBER-2022-1614-3508302

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	27 MAY 2021 00:01
Patient Cloud Close Date & Time	31 MAY 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	**DAY 264**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Date and time of submission	
Patient Cloud Open Date & Time	03 JUN 2021 00:01
Patient Cloud Close Date & Time	07 JUN 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	10 JUN 2021 00:01
Patient Cloud Close Date & Time	14 JUN 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	**DAY 278**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	17 JUN 2021 00:01
Patient Cloud Close Date & Time	21 JUN 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	24 JUN 2021 00:01
Patient Cloud Close Date & Time	28 JUN 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-3508312

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	01 JUL 2021 00:01
Patient Cloud Close Date & Time	05 JUL 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT   DAY 299

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	08 JUL 2021 00:01
Patient Cloud Close Date & Time	12 JUL 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	**DAY 306**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2021 00:01
Patient Cloud Close Date & Time	19 JUL 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	**DAY 313**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

FDA-CBER-2022-1614-3508318

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	22 JUL 2021 00:01
Patient Cloud Close Date & Time	26 JUL 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	**DAY 320**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Date and time of submission	
Patient Cloud Open Date & Time	29 JUL 2021 00:01
Patient Cloud Close Date & Time	02 AUG 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	**DAY 327**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	05 AUG 2021 00:01
Patient Cloud Close Date & Time	09 AUG 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-3508324

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	12 AUG 2021 00:01
Patient Cloud Close Date & Time	16 AUG 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	19 AUG 2021 00:01
Patient Cloud Close Date & Time	23 AUG 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	**DAY 348**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	26 AUG 2021 00:01
Patient Cloud Close Date & Time	30 AUG 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	**DAY 355**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	02 SEP 2021 00:01
Patient Cloud Close Date & Time	06 SEP 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	**DAY 362**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-3508332

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	09 SEP 2021 00:01
Patient Cloud Close Date & Time	13 SEP 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	16 SEP 2021 00:01
Patient Cloud Close Date & Time	20 SEP 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-3508336

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	23 SEP 2021 00:01
Patient Cloud Close Date & Time	27 SEP 2021 23:59

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-3508338

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	30 SEP 2021 00:01
Patient Cloud Close Date & Time	04 OCT 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT DAY 390

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	07 OCT 2021 00:01
Patient Cloud Close Date & Time	11 OCT 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	**DAY 397**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	21 OCT 2021 00:01
Patient Cloud Close Date & Time	25 OCT 2021 23:59

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 411

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	28 OCT 2021 00:01
Patient Cloud Close Date & Time	01 NOV 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT DAY 418

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-3508348

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Date and time of submission	
Patient Cloud Open Date & Time	04 NOV 2021 00:01
Patient Cloud Close Date & Time	08 NOV 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT DAY 425

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-3508350

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	11 NOV 2021 00:01
Patient Cloud Close Date & Time	15 NOV 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	18 NOV 2021 00:01
Patient Cloud Close Date & Time	22 NOV 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-3508354

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	25 NOV 2021 00:01
Patient Cloud Close Date & Time	29 NOV 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT DAY 446

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Date and time of submission	
Patient Cloud Open Date & Time	02 DEC 2021 00:01
Patient Cloud Close Date & Time	06 DEC 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 453

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	09 DEC 2021 00:01
Patient Cloud Close Date & Time	13 DEC 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	**DAY 460**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭘
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭘
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	16 DEC 2021 00:01
Patient Cloud Close Date & Time	20 DEC 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT DAY 467

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	23 DEC 2021 00:01
Patient Cloud Close Date & Time	27 DEC 2021 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	30 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT **DAY 481**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-3508366

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	06 JAN 2022 00:01
Patient Cloud Close Date & Time	10 JAN 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	13 JAN 2022 00:01
Patient Cloud Close Date & Time	17 JAN 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕
	Yes ⭕
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕
	Yes ⭕
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕
	Yes ⭕

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕
	Yes ⭕

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	20 JAN 2022 00:01
Patient Cloud Close Date & Time	24 JAN 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 502

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-3508372

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	27 JAN 2022 00:01
Patient Cloud Close Date & Time	31 JAN 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 509
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

FDA-CBER-2022-1614-3508374

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	03 FEB 2022 00:01
Patient Cloud Close Date & Time	07 FEB 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	**DAY 516**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	10 FEB 2022 00:01
Patient Cloud Close Date & Time	14 FEB 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	**DAY 523**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	17 FEB 2022 00:01
Patient Cloud Close Date & Time	21 FEB 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	24 FEB 2022 00:01
Patient Cloud Close Date & Time	28 FEB 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 537

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-3508382

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	03 MAR 2022 00:01
Patient Cloud Close Date & Time	07 MAR 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	10 MAR 2022 00:01
Patient Cloud Close Date & Time	14 MAR 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT DAY 551

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	17 MAR 2022 00:01
Patient Cloud Close Date & Time	21 MAR 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT   DAY 558

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⚪
Date and time of submission	
Patient Cloud Open Date & Time	24 MAR 2022 00:01
Patient Cloud Close Date & Time	28 MAR 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	**DAY 565**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⵔ Yes ⵔ
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⵔ Yes ⵔ
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⵔ
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⵔ Yes ⵔ

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⵔ
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⵔ Yes ⵔ

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Date and time of submission	
Patient Cloud Open Date & Time	31 MAR 2022 00:01
Patient Cloud Close Date & Time	04 APR 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	**DAY 572**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Date and time of submission	
Patient Cloud Open Date & Time	07 APR 2022 00:01
Patient Cloud Close Date & Time	11 APR 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-3508394

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	14 APR 2022 00:01
Patient Cloud Close Date & Time	18 APR 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 586

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	21 APR 2022 00:01
Patient Cloud Close Date & Time	25 APR 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	**DAY 593**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	28 APR 2022 00:01
Patient Cloud Close Date & Time	02 MAY 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT — DAY 600

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	05 MAY 2022 00:01
Patient Cloud Close Date & Time	09 MAY 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT   DAY 607

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	12 MAY 2022 00:01
Patient Cloud Close Date & Time	16 MAY 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Date and time of submission	
Patient Cloud Open Date & Time	19 MAY 2022 00:01
Patient Cloud Close Date & Time	23 MAY 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-3508406

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	26 MAY 2022 00:01
Patient Cloud Close Date & Time	30 MAY 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

FDA-CBER-2022-1614-3508408

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ○
Date and time of submission	
Patient Cloud Open Date & Time	02 JUN 2022 00:01
Patient Cloud Close Date & Time	06 JUN 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	09 JUN 2022 00:01
Patient Cloud Close Date & Time	13 JUN 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	16 JUN 2022 00:01
Patient Cloud Close Date & Time	20 JUN 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT   DAY 649

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	23 JUN 2022 00:01
Patient Cloud Close Date & Time	27 JUN 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT   DAY 656

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	30 JUN 2022 00:01
Patient Cloud Close Date & Time	04 JUL 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⚪
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
Fever (Temperature $\geq$ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⚪
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪

FDA-CBER-2022-1614-3508418

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	07 JUL 2022 00:01
Patient Cloud Close Date & Time	11 JUL 2022 23:59

TIMEPOINT   DAY 670

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	14 JUL 2022 00:01
Patient Cloud Close Date & Time	18 JUL 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 677
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	**DAY 684**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	28 JUL 2022 00:01
Patient Cloud Close Date & Time	01 AUG 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 691

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	04 AUG 2022 00:01
Patient Cloud Close Date & Time	08 AUG 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT DAY 698

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭘
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭘
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	11 AUG 2022 00:01
Patient Cloud Close Date & Time	15 AUG 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	18 AUG 2022 00:01
Patient Cloud Close Date & Time	22 AUG 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	**DAY 712**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	25 AUG 2022 00:01
Patient Cloud Close Date & Time	29 AUG 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

FDA-CBER-2022-1614-3508434

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	01 SEP 2022 00:01
Patient Cloud Close Date & Time	05 SEP 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	08 SEP 2022 00:01
Patient Cloud Close Date & Time	12 SEP 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-3508438

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	15 SEP 2022 00:01
Patient Cloud Close Date & Time	19 SEP 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 740

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	22 SEP 2022 00:01
Patient Cloud Close Date & Time	26 SEP 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	29 SEP 2022 00:01
Patient Cloud Close Date & Time	03 OCT 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	06 OCT 2022 00:01
Patient Cloud Close Date & Time	10 OCT 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT DAY 761

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

FDA-CBER-2022-1614-3508446

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2022 00:01
Patient Cloud Close Date & Time	17 OCT 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT   DAY 768

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
Fever (Temperature $\geq$ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	20 OCT 2022 00:01
Patient Cloud Close Date & Time	24 OCT 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT   DAY 775

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	27 OCT 2022 00:01
Patient Cloud Close Date & Time	31 OCT 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 782

| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No ◯ |
| | Yes ◯ |

| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No ◯ |
| | Yes ◯ |

| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately ◯ |

| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No ◯ |
| | Yes ◯ |

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately ◯ |

| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No ◯ |
| | Yes ◯ |

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	03 NOV 2022 00:01
Patient Cloud Close Date & Time	07 NOV 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT	DAY 789

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ⃝
Yes ⃝

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ⃝
Yes ⃝

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ⃝

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ⃝
Yes ⃝

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ⃝

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ⃝
Yes ⃝

FDA-CBER-2022-1614-3508454

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	10 NOV 2022 00:01
Patient Cloud Close Date & Time	14 NOV 2022 23:59

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT   DAY 796

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)   _____

Chills   _____

Cough   _____

Shortness of breath   _____

Difficulty breathing   _____

Fatigue   _____

Muscle aches   _____

Body aches   _____

Headache   _____

New loss of taste   _____

New loss of smell   _____

Sore throat   _____

Congestion   _____

Runny nose   _____

Nausea   _____

Vomiting   _____

Diarrhea   _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	17 NOV 2022 00:01
Patient Cloud Close Date & Time	21 NOV 2022 23:59

US3912163

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:19:18

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission	
No		27 FEB 2021 17:46:09	

US3912163

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) **19 Feb 2021 16:47:42**

Generated On: 10 Jun 2021 10:19:18

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	9 DEC 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3912163

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) **19 Feb 2021 16:47:42**

Generated On: 10 Jun 2021 10:19:18

Is the participant continuing to the next visit?   Yes ●

No ◯

Continuing Flag   1

US3912163
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **19 Feb 2021 16:47:42**
Generated On: 10 Jun 2021 10:19:18

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	14 JAN 2021
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3912163
Folder: Safety Call Day 119 (1)
Form: Continuing
Data signed: (b) (4) **19 Feb 2021 16:47:42**
Generated On: 10 Jun 2021 10:19:18

Is the participant continuing to the next visit?   Yes ⬤

                                                          No ◯

Continuing Flag   1

US3912163

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) **11 Mar 2021 17:48:51**

Generated On: 10 Jun 2021 10:19:18

| Was Contact Attempted? | Yes ● |
| | No ○ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 5 FEB 2021 |

| Please select one status for the follow-up contact | Contact Made ● |
| | Contact Not Made ○ |

Comments

If Contact Not Made, please provide Comments

US3912163

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) **09 Mar 2021 19:58:36**

Generated On: 10 Jun 2021 10:19:18

Is the participant continuing to the next visit? Yes ●

No ◯

Continuing Flag 1

US3912163
Folder: Safety Call Day 179 (1)
Form: Safety Call
Data signed: (b) (4) **18 Mar 2021 18:27:08**
Generated On: 10 Jun 2021 10:19:18

Was Contact Attempted?   Yes ●

                                                                No ○

Date of Contact or Contact Attempt *(dd MMM yyyy)*   15 MAR 2021

Please select one status for the follow-up contact   Contact Made ●

                                                        Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3912163

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) **18 Mar 2021 18:27:08**

Generated On: 10 Jun 2021 10:19:18

Is the participant continuing to the next visit? Yes ●

No ◯

Continuing Flag 1

| Was this visit performed? | Yes ◯ |
| | No ◯ |

Visit date (dd MMM yyyy) _____

| Was visit performed at the participant's home or at the clinic? | Home ◯ |
| | Clinic ◯ |

Folder OID _____

Were vital signs assessed?	Yes ◯
	No ◯

Date of assessment *(dd MMM yyyy)*	_____
Time of assessment *(00:00-23:59)*	_____
Vital Signs Date and Time (derived)	_____
Temperature *(xxx.x)*	_____

Route of measurement	Oral ◯
	Axillary ◯
	Other ◯

If Other, specify	_____
Pulse *(xxx)*	_____
Pulse units	_____
Respiratory Rate *(xxx)*	_____
Respiratory Rate units	_____
Systolic Blood Pressure *(xxx)*	_____
Systolic Blood Pressure units	_____
Diastolic Blood Pressure *(xxx)*	_____
Diastolic Blood Pressure units	_____
Height (derived)	_____
Weight (derived)	_____

Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 10:19:18

Was the physical examination performed?   Yes ◯

No ◯

Date of examination *(dd MMM yyyy)*

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

Was the sample collected?   Yes ⬭

                                                                             No ⬭

Collection date *(dd MMM yyyy)*

Collection time *(00:00-23:59)*

Collection date and time (derived)

Is the participant continuing to the next visit?   Yes ◯

                                                            No ◯

Continuing Flag

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: COVID-19 Contact
Data signed: (b) (4) **19 Feb 2021 16:47:00**
Generated On: 10 Jun 2021 10:19:18

Date of Contact	9 DEC 2020
Time of Contact	10:00
Date and Time of Contact (derived)	9 DEC 2020 10:00

Type of Contact

Clinic Visit - Scheduled ◯

Clinical Visit - Unscheduled ◯

Safety Call ⬤

Convalescent Tele-visit ◯

Has the subject reported symptoms of SARS-COV-2?

Yes ⬤

No ◯

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (1)

Data signed: [(b) (4)] 20 Apr 2021 18:51:44

Generated On: 10 Jun 2021 10:19:18

Symptom Day

Day 1	●
Day 2	○
Day 3	○
Day 4	○
Day 5	○
Day 6	○
Day 7	○
Day 8	○
Day 9	○
Day 10	○
Day 11	○
Day 12	○
Day 13	○
Day 14	○
Day 15	○
Day 16	○
Day 17	○
Day 18	○
Day 19	○
Day 20	○
Day 21	○
Day 22	○
Day 23	○
Day 24	○
Day 25	○
Day 26	○
Day 27	○
Day 28	○
Day 29	○
Day 30	○
Day 31	○
Day 32	○

	Day 33 ⬭
	Day 34 ⬭
	Day 35 ⬭
	Day 36 ⬭
	Day 37 ⬭
	Day 38 ⬭
	Day 39 ⬭
	Day 40 ⬭
Date	04 DEC 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	ND - Not Done
Chills	None ⬭
	Mild ⬤
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Cough	None ⬭
	Mild ⬤
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Shortness of Breath	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Difficulty Breathing	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭

Not Done ○

Fatigue None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Muscle Aches (Myalgia) None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Body Aches None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Headache None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

New Loss of Taste None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

New Loss of Smell None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Nasal Congestion

- None
- Mild ●
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild ●
- Moderate
- Severe
- Not Done

Nausea

- None ●
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None ●
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None ●
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None ●
- Mild
- Moderate
- Severe
- Not Done

Symptom Day

Day 1 ◯
Day 2 ⬤
Day 3 ◯
Day 4 ◯
Day 5 ◯
Day 6 ◯
Day 7 ◯
Day 8 ◯
Day 9 ◯
Day 10 ◯
Day 11 ◯
Day 12 ◯
Day 13 ◯
Day 14 ◯
Day 15 ◯
Day 16 ◯
Day 17 ◯
Day 18 ◯
Day 19 ◯
Day 20 ◯
Day 21 ◯
Day 22 ◯
Day 23 ◯
Day 24 ◯
Day 25 ◯
Day 26 ◯
Day 27 ◯
Day 28 ◯
Day 29 ◯
Day 30 ◯
Day 31 ◯
Day 32 ◯

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	05 DEC 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	ND - Not Done
Chills	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ◯
	Mild ●
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ●
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ◯

Fatigue None ●
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Muscle Aches (Myalgia) None ●
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Body Aches None ●
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Headache None ●
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

New Loss of Taste None ●
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

New Loss of Smell None ●
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Nasal Congestion

None ⭕
Mild ⚫
Moderate ⭕
Severe ⭕
Not Done ⭕

Runny Nose (Rhinorrhea)

None ⭕
Mild ⚫
Moderate ⭕
Severe ⭕
Not Done ⭕

Nausea

None ⚫
Mild ⭕
Moderate ⭕
Severe ⭕
Not Done ⭕

Vomiting

None ⚫
Mild ⭕
Moderate ⭕
Severe ⭕
Not Done ⭕

Diarrhea

None ⚫
Mild ⭕
Moderate ⭕
Severe ⭕
Not Done ⭕

Sore Throat

None ⚫
Mild ⭕
Moderate ⭕
Severe ⭕
Not Done ⭕

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (3)
Data signed: (b) (4) 20 Apr 2021 18:51:44
Generated On: 10 Jun 2021 10:19:18

Symptom Day

Day 1	◯
Day 2	◯
Day 3	⬤
Day 4	◯
Day 5	◯
Day 6	◯
Day 7	◯
Day 8	◯
Day 9	◯
Day 10	◯
Day 11	◯
Day 12	◯
Day 13	◯
Day 14	◯
Day 15	◯
Day 16	◯
Day 17	◯
Day 18	◯
Day 19	◯
Day 20	◯
Day 21	◯
Day 22	◯
Day 23	◯
Day 24	◯
Day 25	◯
Day 26	◯
Day 27	◯
Day 28	◯
Day 29	◯
Day 30	◯
Day 31	◯
Day 32	◯

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	06 DEC 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	ND - Not Done
Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ◯
	Mild ⬤
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ⭘

Fatigue None ⚫

Mild ⭘

Moderate ⭘

Severe ⭘

Not Done ⭘

Muscle Aches (Myalgia) None ⚫

Mild ⭘

Moderate ⭘

Severe ⭘

Not Done ⭘

Body Aches None ⚫

Mild ⭘

Moderate ⭘

Severe ⭘

Not Done ⭘

Headache None ⚫

Mild ⭘

Moderate ⭘

Severe ⭘

Not Done ⭘

New Loss of Taste None ⚫

Mild ⭘

Moderate ⭘

Severe ⭘

Not Done ⭘

New Loss of Smell None ⚫

Mild ⭘

Moderate ⭘

Severe ⭘

Not Done ⭘

Nasal Congestion	
	None ○
	Mild ●
	Moderate ○
	Severe ○
	Not Done ○

Runny Nose (Rhinorrhea)	
	None ○
	Mild ●
	Moderate ○
	Severe ○
	Not Done ○

Nausea	
	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○

Vomiting	
	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○

Diarrhea	
	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○

Sore Throat	
	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○

Symptom Day

Day 1 ◯
Day 2 ◯
Day 3 ◯
Day 4 ⬤
Day 5 ◯
Day 6 ◯
Day 7 ◯
Day 8 ◯
Day 9 ◯
Day 10 ◯
Day 11 ◯
Day 12 ◯
Day 13 ◯
Day 14 ◯
Day 15 ◯
Day 16 ◯
Day 17 ◯
Day 18 ◯
Day 19 ◯
Day 20 ◯
Day 21 ◯
Day 22 ◯
Day 23 ◯
Day 24 ◯
Day 25 ◯
Day 26 ◯
Day 27 ◯
Day 28 ◯
Day 29 ◯
Day 30 ◯
Day 31 ◯
Day 32 ◯

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	07 DEC 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	ND - Not Done
Chills	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ◯
	Mild ●
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ●
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ⬭

Fatigue   None ⬤

Mild ⬭

Moderate ⬭

Severe ⬭

Not Done ⬭

Muscle Aches (Myalgia)   None ⬤

Mild ⬭

Moderate ⬭

Severe ⬭

Not Done ⬭

Body Aches   None ⬤

Mild ⬭

Moderate ⬭

Severe ⬭

Not Done ⬭

Headache   None ⬤

Mild ⬭

Moderate ⬭

Severe ⬭

Not Done ⬭

New Loss of Taste   None ⬤

Mild ⬭

Moderate ⬭

Severe ⬭

Not Done ⬭

New Loss of Smell   None ⬤

Mild ⬭

Moderate ⬭

Severe ⬭

Not Done ⬭

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) **20 Apr 2021 18:51:44**

Generated On: 10 Jun 2021 10:19:18

Nasal Congestion

- None ○
- Mild ●
- Moderate ○
- Severe ○
- Not Done ○

Runny Nose (Rhinorrhea)

- None ○
- Mild ●
- Moderate ○
- Severe ○
- Not Done ○

Nausea

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Vomiting

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Diarrhea

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Sore Throat

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Symptom Day

Day 1 ◯
Day 2 ◯
Day 3 ◯
Day 4 ◯
Day 5 ⬤
Day 6 ◯
Day 7 ◯
Day 8 ◯
Day 9 ◯
Day 10 ◯
Day 11 ◯
Day 12 ◯
Day 13 ◯
Day 14 ◯
Day 15 ◯
Day 16 ◯
Day 17 ◯
Day 18 ◯
Day 19 ◯
Day 20 ◯
Day 21 ◯
Day 22 ◯
Day 23 ◯
Day 24 ◯
Day 25 ◯
Day 26 ◯
Day 27 ◯
Day 28 ◯
Day 29 ◯
Day 30 ◯
Day 31 ◯
Day 32 ◯

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	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	08 DEC 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	ND - Not Done
Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ◯
	Mild ⬤
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ◯

Fatigue None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Muscle Aches (Myalgia) None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Body Aches None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Headache None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Taste None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Smell None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Nasal Congestion

None ◯
Mild ⬤
Moderate ◯
Severe ◯
Not Done ◯

Runny Nose (Rhinorrhea)

None ◯
Mild ⬤
Moderate ◯
Severe ◯
Not Done ◯

Nausea

None ⬤
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Vomiting

None ⬤
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Diarrhea

None ⬤
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Sore Throat

None ⬤
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 20 Apr 2021 18:51:44

Generated On: 10 Jun 2021 10:19:18

Symptom Day

Day 1	◯
Day 2	◯
Day 3	◯
Day 4	◯
Day 5	◯
Day 6	●
Day 7	◯
Day 8	◯
Day 9	◯
Day 10	◯
Day 11	◯
Day 12	◯
Day 13	◯
Day 14	◯
Day 15	◯
Day 16	◯
Day 17	◯
Day 18	◯
Day 19	◯
Day 20	◯
Day 21	◯
Day 22	◯
Day 23	◯
Day 24	◯
Day 25	◯
Day 26	◯
Day 27	◯
Day 28	◯
Day 29	◯
Day 30	◯
Day 31	◯
Day 32	◯

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	09 DEC 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	ND - Not Done
Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ◯
	Mild ⬤
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

FDA-CBER-2022-1614-3508494

Not Done ○

Fatigue None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Muscle Aches (Myalgia) None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Body Aches None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Headache None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

New Loss of Taste None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

New Loss of Smell None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Nasal Congestion

None ⭘
Mild ⬤
Moderate ⭘
Severe ⭘
Not Done ⭘

Runny Nose (Rhinorrhea)

None ⭘
Mild ⬤
Moderate ⭘
Severe ⭘
Not Done ⭘

Nausea

None ⭘
Mild ⬤
Moderate ⭘
Severe ⭘
Not Done ⭘

Vomiting

None ⬤
Mild ⭘
Moderate ⭘
Severe ⭘
Not Done ⭘

Diarrhea

None ⬤
Mild ⭘
Moderate ⭘
Severe ⭘
Not Done ⭘

Sore Throat

None ⬤
Mild ⭘
Moderate ⭘
Severe ⭘
Not Done ⭘

Symptom Day

Day 1	◯
Day 2	◯
Day 3	◯
Day 4	◯
Day 5	◯
Day 6	◯
Day 7	⬤
Day 8	◯
Day 9	◯
Day 10	◯
Day 11	◯
Day 12	◯
Day 13	◯
Day 14	◯
Day 15	◯
Day 16	◯
Day 17	◯
Day 18	◯
Day 19	◯
Day 20	◯
Day 21	◯
Day 22	◯
Day 23	◯
Day 24	◯
Day 25	◯
Day 26	◯
Day 27	◯
Day 28	◯
Day 29	◯
Day 30	◯
Day 31	◯
Day 32	◯

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Data signed: [(b) (4)] **20 Apr 2021 18:51:44**

Generated On: 10 Jun 2021 10:19:18

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯

Date	10 DEC 2020
Assessment Not Done	False
O2 Saturation	95 %
O2 Saturation Units	%
Temperature	37.2 C
Chills	None ◯
	Mild ⬤
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ◯
	Mild ⬤
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

PRODUCTION RELEASE (v12.003
EAB) (1725)

FDA-CBER-2022-1614-3508498

Not Done ⚪

Fatigue

None ⚪

Mild ⚫

Moderate ⚪

Severe ⚪

Not Done ⚪

Muscle Aches (Myalgia)

None ⚫

Mild ⚪

Moderate ⚪

Severe ⚪

Not Done ⚪

Body Aches

None ⚪

Mild ⚫

Moderate ⚪

Severe ⚪

Not Done ⚪

Headache

None ⚫

Mild ⚪

Moderate ⚪

Severe ⚪

Not Done ⚪

New Loss of Taste

None ⚫

Mild ⚪

Moderate ⚪

Severe ⚪

Not Done ⚪

New Loss of Smell

None ⚫

Mild ⚪

Moderate ⚪

Severe ⚪

Not Done ⚪

Nasal Congestion

- None ⚪
- Mild ⚫
- Moderate ⚪
- Severe ⚪
- Not Done ⚪

Runny Nose (Rhinorrhea)

- None ⚫
- Mild ⚪
- Moderate ⚪
- Severe ⚪
- Not Done ⚪

Nausea

- None ⚫
- Mild ⚪
- Moderate ⚪
- Severe ⚪
- Not Done ⚪

Vomiting

- None ⚫
- Mild ⚪
- Moderate ⚪
- Severe ⚪
- Not Done ⚪

Diarrhea

- None ⚫
- Mild ⚪
- Moderate ⚪
- Severe ⚪
- Not Done ⚪

Sore Throat

- None ⚫
- Mild ⚪
- Moderate ⚪
- Severe ⚪
- Not Done ⚪

FDA-CBER-2022-1614-3508500

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (8)
Data signed: (b) (4)   20 Apr 2021 18:51:44
Generated On: 10 Jun 2021 10:19:18

Symptom Day

Day 1	○
Day 2	○
Day 3	○
Day 4	○
Day 5	○
Day 6	○
Day 7	○
Day 8	●
Day 9	○
Day 10	○
Day 11	○
Day 12	○
Day 13	○
Day 14	○
Day 15	○
Day 16	○
Day 17	○
Day 18	○
Day 19	○
Day 20	○
Day 21	○
Day 22	○
Day 23	○
Day 24	○
Day 25	○
Day 26	○
Day 27	○
Day 28	○
Day 29	○
Day 30	○
Day 31	○
Day 32	○

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	11 DEC 2020
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	36.9 C
Chills	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ●
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ◯

Fatigue   None ⬤
                                                    Mild ◯
                                                Moderate ◯
                                                  Severe ◯
                                                Not Done ◯

Muscle Aches (Myalgia)   None ⬤
                                                    Mild ◯
                                                Moderate ◯
                                                  Severe ◯
                                                Not Done ◯

Body Aches   None ⬤
                                                    Mild ◯
                                                Moderate ◯
                                                  Severe ◯
                                                Not Done ◯

Headache   None ⬤
                                                    Mild ◯
                                                Moderate ◯
                                                  Severe ◯
                                                Not Done ◯

New Loss of Taste   None ⬤
                                                    Mild ◯
                                                Moderate ◯
                                                  Severe ◯
                                                Not Done ◯

New Loss of Smell   None ⬤
                                                    Mild ◯
                                                Moderate ◯
                                                  Severe ◯
                                                Not Done ◯

Nasal Congestion

None ○
Mild ●
Moderate ○
Severe ○
Not Done ○

Runny Nose (Rhinorrhea)

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Nausea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Vomiting

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Diarrhea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Sore Throat

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

FDA-CBER-2022-1614-3508504

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 20 Apr 2021 18:51:44

Generated On: 10 Jun 2021 10:19:18

Symptom Day

Day 1 ◯
Day 2 ◯
Day 3 ◯
Day 4 ◯
Day 5 ◯
Day 6 ◯
Day 7 ◯
Day 8 ◯
Day 9 ⬤
Day 10 ◯
Day 11 ◯
Day 12 ◯
Day 13 ◯
Day 14 ◯
Day 15 ◯
Day 16 ◯
Day 17 ◯
Day 18 ◯
Day 19 ◯
Day 20 ◯
Day 21 ◯
Day 22 ◯
Day 23 ◯
Day 24 ◯
Day 25 ◯
Day 26 ◯
Day 27 ◯
Day 28 ◯
Day 29 ◯
Day 30 ◯
Day 31 ◯
Day 32 ◯

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	12 DEC 2020
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	36.6 C
Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ○

Fatigue

None ○

Mild ○

Moderate ○

Severe ●

Not Done ○

Muscle Aches (Myalgia)

None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Body Aches

None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Headache

None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

New Loss of Taste

None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

New Loss of Smell

None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Nasal Congestion

- None ◯
- Mild ⬤
- Moderate ◯
- Severe ◯
- Not Done ◯

Runny Nose (Rhinorrhea)

- None ◯
- Mild ⬤
- Moderate ◯
- Severe ◯
- Not Done ◯

Nausea

- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Vomiting

- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Diarrhea

- None ◯
- Mild ⬤
- Moderate ◯
- Severe ◯
- Not Done ◯

Sore Throat

- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4)   **20 Apr 2021 18:51:44**

Generated On: 10 Jun 2021 10:19:18

Symptom Day

Day 1	◯
Day 2	◯
Day 3	◯
Day 4	◯
Day 5	◯
Day 6	◯
Day 7	◯
Day 8	◯
Day 9	◯
Day 10	⬤
Day 11	◯
Day 12	◯
Day 13	◯
Day 14	◯
Day 15	◯
Day 16	◯
Day 17	◯
Day 18	◯
Day 19	◯
Day 20	◯
Day 21	◯
Day 22	◯
Day 23	◯
Day 24	◯
Day 25	◯
Day 26	◯
Day 27	◯
Day 28	◯
Day 29	◯
Day 30	◯
Day 31	◯
Day 32	◯

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	13 DEC 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	36.9 C
Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

	Not Done ⬭
Fatigue	None ⬭
	Mild ⬭
	Moderate ⬭
	Severe ⬤
	Not Done ⬭
Muscle Aches (Myalgia)	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Body Aches	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Headache	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
New Loss of Taste	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
New Loss of Smell	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭

Nasal Congestion

- None ○
- Mild ●
- Moderate ○
- Severe ○
- Not Done ○

Runny Nose (Rhinorrhea)

- None ○
- Mild ●
- Moderate ○
- Severe ○
- Not Done ○

Nausea

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Vomiting

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Diarrhea

- None ○
- Mild ●
- Moderate ○
- Severe ○
- Not Done ○

Sore Throat

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Symptom Day

Day 1 ◯
Day 2 ◯
Day 3 ◯
Day 4 ◯
Day 5 ◯
Day 6 ◯
Day 7 ◯
Day 8 ◯
Day 9 ◯
Day 10 ◯
Day 11 ⬤
Day 12 ◯
Day 13 ◯
Day 14 ◯
Day 15 ◯
Day 16 ◯
Day 17 ◯
Day 18 ◯
Day 19 ◯
Day 20 ◯
Day 21 ◯
Day 22 ◯
Day 23 ◯
Day 24 ◯
Day 25 ◯
Day 26 ◯
Day 27 ◯
Day 28 ◯
Day 29 ◯
Day 30 ◯
Day 31 ◯
Day 32 ◯

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	14 DEC 2020
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	36.9 C
Chills	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ●
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ○

Fatigue

None ○
Mild ○
Moderate ●
Severe ○
Not Done ○

Muscle Aches (Myalgia)

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Body Aches

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Headache

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

New Loss of Taste

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

New Loss of Smell

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Nasal Congestion

- None ○
- Mild ●
- Moderate ○
- Severe ○
- Not Done ○

Runny Nose (Rhinorrhea)

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Nausea

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Vomiting

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Diarrhea

- None ○
- Mild ●
- Moderate ○
- Severe ○
- Not Done ○

Sore Throat

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

FDA-CBER-2022-1614-3508516

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (12)
Data signed: [(b) (4)   ] **20 Apr 2021 18:51:44**
Generated On: 10 Jun 2021 10:19:18

Symptom Day

Day 1 ○
Day 2 ○
Day 3 ○
Day 4 ○
Day 5 ○
Day 6 ○
Day 7 ○
Day 8 ○
Day 9 ○
Day 10 ○
Day 11 ○
Day 12 ●
Day 13 ○
Day 14 ○
Day 15 ○
Day 16 ○
Day 17 ○
Day 18 ○
Day 19 ○
Day 20 ○
Day 21 ○
Day 22 ○
Day 23 ○
Day 24 ○
Day 25 ○
Day 26 ○
Day 27 ○
Day 28 ○
Day 29 ○
Day 30 ○
Day 31 ○
Day 32 ○

	Day 33 ⬭
	Day 34 ⬭
	Day 35 ⬭
	Day 36 ⬭
	Day 37 ⬭
	Day 38 ⬭
	Day 39 ⬭
	Day 40 ⬭
Date	15 DEC 2020
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	36.9 C
Chills	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Cough	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Shortness of Breath	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Difficulty Breathing	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭

Not Done ○

Fatigue

None ○
Mild ○
Moderate ●
Severe ○
Not Done ○

Muscle Aches (Myalgia)

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Body Aches

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Headache

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

New Loss of Taste

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

New Loss of Smell

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Nasal Congestion

- None ◯
- Mild ⬤
- Moderate ◯
- Severe ◯
- Not Done ◯

Runny Nose (Rhinorrhea)

- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Nausea

- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Vomiting

- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Diarrhea

- None ◯
- Mild ⬤
- Moderate ◯
- Severe ◯
- Not Done ◯

Sore Throat

- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Symptom Day

Day 1	○
Day 2	○
Day 3	○
Day 4	○
Day 5	○
Day 6	○
Day 7	○
Day 8	○
Day 9	○
Day 10	○
Day 11	○
Day 12	○
Day 13	●
Day 14	○
Day 15	○
Day 16	○
Day 17	○
Day 18	○
Day 19	○
Day 20	○
Day 21	○
Day 22	○
Day 23	○
Day 24	○
Day 25	○
Day 26	○
Day 27	○
Day 28	○
Day 29	○
Day 30	○
Day 31	○
Day 32	○

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯

Date	16 DEC 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	36.8 C
Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ○

Fatigue

None ○
Mild ○
Moderate ●
Severe ○
Not Done ○

Muscle Aches (Myalgia)

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Body Aches

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Headache

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

New Loss of Taste

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

New Loss of Smell

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Nasal Congestion

- None ⚪
- Mild ⚫
- Moderate ⚪
- Severe ⚪
- Not Done ⚪

Runny Nose (Rhinorrhea)

- None ⚫
- Mild ⚪
- Moderate ⚪
- Severe ⚪
- Not Done ⚪

Nausea

- None ⚫
- Mild ⚪
- Moderate ⚪
- Severe ⚪
- Not Done ⚪

Vomiting

- None ⚫
- Mild ⚪
- Moderate ⚪
- Severe ⚪
- Not Done ⚪

Diarrhea

- None ⚪
- Mild ⚪
- Moderate ⚫
- Severe ⚪
- Not Done ⚪

Sore Throat

- None ⚫
- Mild ⚪
- Moderate ⚪
- Severe ⚪
- Not Done ⚪

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Symptom Day

Day 1	◯
Day 2	◯
Day 3	◯
Day 4	◯
Day 5	◯
Day 6	◯
Day 7	◯
Day 8	◯
Day 9	◯
Day 10	◯
Day 11	◯
Day 12	◯
Day 13	◯
Day 14	●
Day 15	◯
Day 16	◯
Day 17	◯
Day 18	◯
Day 19	◯
Day 20	◯
Day 21	◯
Day 22	◯
Day 23	◯
Day 24	◯
Day 25	◯
Day 26	◯
Day 27	◯
Day 28	◯
Day 29	◯
Day 30	◯
Day 31	◯
Day 32	◯

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	17 DEC 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	36.2 C
Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

	Not Done ○
Fatigue	None ○
	Mild ○
	Moderate ●
	Severe ○
	Not Done ○
Muscle Aches (Myalgia)	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○
Body Aches	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○
Headache	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○
New Loss of Taste	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○
New Loss of Smell	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○

Nasal Congestion

- None ○
- Mild ●
- Moderate ○
- Severe ○
- Not Done ○

Runny Nose (Rhinorrhea)

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Nausea

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Vomiting

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Diarrhea

- None ○
- Mild ●
- Moderate ○
- Severe ○
- Not Done ○

Sore Throat

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Symptom Day

Day 1 ◯
Day 2 ◯
Day 3 ◯
Day 4 ◯
Day 5 ◯
Day 6 ◯
Day 7 ◯
Day 8 ◯
Day 9 ◯
Day 10 ◯
Day 11 ◯
Day 12 ◯
Day 13 ◯
Day 14 ◯
Day 15 ⬤
Day 16 ◯
Day 17 ◯
Day 18 ◯
Day 19 ◯
Day 20 ◯
Day 21 ◯
Day 22 ◯
Day 23 ◯
Day 24 ◯
Day 25 ◯
Day 26 ◯
Day 27 ◯
Day 28 ◯
Day 29 ◯
Day 30 ◯
Day 31 ◯
Day 32 ◯

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯

Date	18 DEC 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	36.3 C
Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

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Not Done ○

Fatigue
- None ○
- Mild ○
- Moderate ●
- Severe ○
- Not Done ○

Muscle Aches (Myalgia)
- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Body Aches
- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Headache
- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

New Loss of Taste
- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

New Loss of Smell
- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Nasal Congestion

- None ( )
- Mild (●)
- Moderate ( )
- Severe ( )
- Not Done ( )

Runny Nose (Rhinorrhea)

- None (●)
- Mild ( )
- Moderate ( )
- Severe ( )
- Not Done ( )

Nausea

- None (●)
- Mild ( )
- Moderate ( )
- Severe ( )
- Not Done ( )

Vomiting

- None (●)
- Mild ( )
- Moderate ( )
- Severe ( )
- Not Done ( )

Diarrhea

- None (●)
- Mild ( )
- Moderate ( )
- Severe ( )
- Not Done ( )

Sore Throat

- None (●)
- Mild ( )
- Moderate ( )
- Severe ( )
- Not Done ( )

Symptom Day

Day 1	◯
Day 2	◯
Day 3	◯
Day 4	◯
Day 5	◯
Day 6	◯
Day 7	◯
Day 8	◯
Day 9	◯
Day 10	◯
Day 11	◯
Day 12	◯
Day 13	◯
Day 14	◯
Day 15	◯
Day 16	●
Day 17	◯
Day 18	◯
Day 19	◯
Day 20	◯
Day 21	◯
Day 22	◯
Day 23	◯
Day 24	◯
Day 25	◯
Day 26	◯
Day 27	◯
Day 28	◯
Day 29	◯
Day 30	◯
Day 31	◯
Day 32	◯

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯

Date	19 DEC 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	36.4 C
Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ○

Fatigue

None ○

Mild ●

Moderate ○

Severe ○

Not Done ○

Muscle Aches (Myalgia)

None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Body Aches

None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Headache

None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

New Loss of Taste

None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

New Loss of Smell

None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (16)

Data signed: 　　　(b) (4)　　　 **20 Apr 2021 18:51:44**

Generated On: 10 Jun 2021 10:19:18

Nasal Congestion	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○

Runny Nose (Rhinorrhea)	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○

Nausea	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○

Vomiting	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○

Diarrhea	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○

Sore Throat	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Data signed: [(b) (4)] **20 Apr 2021 18:51:44**

Generated On: 10 Jun 2021 10:19:18

Symptom Day

Day 1	◯
Day 2	◯
Day 3	◯
Day 4	◯
Day 5	◯
Day 6	◯
Day 7	◯
Day 8	◯
Day 9	◯
Day 10	◯
Day 11	◯
Day 12	◯
Day 13	◯
Day 14	◯
Day 15	◯
Day 16	◯
Day 17	⬤
Day 18	◯
Day 19	◯
Day 20	◯
Day 21	◯
Day 22	◯
Day 23	◯
Day 24	◯
Day 25	◯
Day 26	◯
Day 27	◯
Day 28	◯
Day 29	◯
Day 30	◯
Day 31	◯
Day 32	◯

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	20 DEC 2020
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	36.4 C
Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ○

Fatigue   None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Muscle Aches (Myalgia)   None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Body Aches   None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Headache   None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

New Loss of Taste   None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

New Loss of Smell   None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Nasal Congestion

- None ○
- Mild ●
- Moderate ○
- Severe ○
- Not Done ○

Runny Nose (Rhinorrhea)

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Nausea

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Vomiting

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Diarrhea

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Sore Throat

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Symptom Day

Day 1	◯
Day 2	◯
Day 3	◯
Day 4	◯
Day 5	◯
Day 6	◯
Day 7	◯
Day 8	◯
Day 9	◯
Day 10	◯
Day 11	◯
Day 12	◯
Day 13	◯
Day 14	◯
Day 15	◯
Day 16	◯
Day 17	◯
Day 18	⬤
Day 19	◯
Day 20	◯
Day 21	◯
Day 22	◯
Day 23	◯
Day 24	◯
Day 25	◯
Day 26	◯
Day 27	◯
Day 28	◯
Day 29	◯
Day 30	◯
Day 31	◯
Day 32	◯

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	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	21 DEC 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	97.4 F
Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ◯

Fatigue

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Muscle Aches (Myalgia)

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Body Aches

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Headache

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Taste

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Smell

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Nasal Congestion

None ○
Mild ●
Moderate ○
Severe ○
Not Done ○

Runny Nose (Rhinorrhea)

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Nausea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Vomiting

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Diarrhea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Sore Throat

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

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Symptom Day

Day 1 ◯
Day 2 ◯
Day 3 ◯
Day 4 ◯
Day 5 ◯
Day 6 ◯
Day 7 ◯
Day 8 ◯
Day 9 ◯
Day 10 ◯
Day 11 ◯
Day 12 ◯
Day 13 ◯
Day 14 ◯
Day 15 ◯
Day 16 ◯
Day 17 ◯
Day 18 ◯
Day 19 ⬤
Day 20 ◯
Day 21 ◯
Day 22 ◯
Day 23 ◯
Day 24 ◯
Day 25 ◯
Day 26 ◯
Day 27 ◯
Day 28 ◯
Day 29 ◯
Day 30 ◯
Day 31 ◯
Day 32 ◯

	Day 33 ⭘
	Day 34 ⭘
	Day 35 ⭘
	Day 36 ⭘
	Day 37 ⭘
	Day 38 ⭘
	Day 39 ⭘
	Day 40 ⭘
Date	22 DEC 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	97.4 F
Chills	None ⬤
	Mild ⭘
	Moderate ⭘
	Severe ⭘
	Not Done ⭘
Cough	None ⬤
	Mild ⭘
	Moderate ⭘
	Severe ⭘
	Not Done ⭘
Shortness of Breath	None ⬤
	Mild ⭘
	Moderate ⭘
	Severe ⭘
	Not Done ⭘
Difficulty Breathing	None ⬤
	Mild ⭘
	Moderate ⭘
	Severe ⭘

Not Done ⚪

Fatigue

None ⚪

Mild ⚫

Moderate ⚪

Severe ⚪

Not Done ⚪

Muscle Aches (Myalgia)

None ⚫

Mild ⚪

Moderate ⚪

Severe ⚪

Not Done ⚪

Body Aches

None ⚫

Mild ⚪

Moderate ⚪

Severe ⚪

Not Done ⚪

Headache

None ⚫

Mild ⚪

Moderate ⚪

Severe ⚪

Not Done ⚪

New Loss of Taste

None ⚫

Mild ⚪

Moderate ⚪

Severe ⚪

Not Done ⚪

New Loss of Smell

None ⚫

Mild ⚪

Moderate ⚪

Severe ⚪

Not Done ⚪

FDA-CBER-2022-1614-3508547

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Data signed: [(b) (4)] **20 Apr 2021 18:51:44**

Generated On: 10 Jun 2021 10:19:18

Nasal Congestion

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Runny Nose (Rhinorrhea)

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Nausea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Vomiting

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Diarrhea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Sore Throat

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Date of Visit	10 DEC 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ●
	No ○
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ●
	No ○
Date of Test	10 DEC 2020
Type of Test Performed	Nasopharyngeal Swab ○
	Nasal Swab ●
	Saliva Test ○
	Other ○
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ○
	No ●
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes ○
	No ○
COVID-19 Positive (CSA Programming Field Only)	1

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Did the subject have Respiratory Rates $\geq$ 30 per Minute?　　Yes ◯　No ●

If Yes, provide:

　Start Date ＿＿＿＿＿＿＿＿＿＿

　End Date ＿＿＿＿＿＿＿＿＿＿

　Respiratory Rate ＿＿＿＿＿＿＿＿＿＿

Did the subject have Heart Rate $\geq$ 125 beats per minute　　Yes ◯　No ●

If Yes, provide:

　Start Date ＿＿＿＿＿＿＿＿＿＿

　End Date ＿＿＿＿＿＿＿＿＿＿

　Heart Rate ＿＿＿＿＿＿＿＿＿＿

Did the subject have Oxygen Saturation of SpO2 $\leq$ 93% on room air at sea level?　　Yes ◯　No ●

If Yes, provide:

　Start Date ＿＿＿＿＿＿＿＿＿＿

　End Date ＿＿＿＿＿＿＿＿＿＿

　Oxygen Saturation ＿＿＿＿＿＿＿＿＿＿

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?　　Yes ◯　No ●

If Yes, provide:

　Start Date ＿＿＿＿＿＿＿＿＿＿

　End Date ＿＿＿＿＿＿＿＿＿＿

　PaO2 ＿＿＿＿＿＿＿＿＿＿

Did the subject have Respiratory failure?　　Yes ◯　No ●

　Start Date ＿＿＿＿＿＿＿＿＿＿

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?　　Yes ◯　No ●

　Start Date ＿＿＿＿＿＿＿＿＿＿

If Yes to either Did subject require any of the following:

Ventilator Support:

High-Flow Oxygen?	Yes ◯ No ◯
Start Date	_____
End Date	_____
Non-Invasive Ventilation?	Yes ◯ No ◯
Start Date	_____
End Date	_____
Mechanical Ventilation?	Yes ◯ No ◯
Start Date	_____
End Date	_____
ECMO?	Yes ◯ No ◯
Start Date	_____
End Date	_____

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg	Yes ◯ No ◯
Start Date	_____
End Date	_____
Evidence of Shock Requires Vasopressors	Yes ◯ No ◯
Start Date	_____
End Date	_____
Acute Renal Dysfunction?	Yes ◯ No ◯
Start Date	_____

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Hepatic Dysfunction?   Yes ◯

                                                        No ◯

   Start Date   _____

Neurologic Dysfunction?   Yes ◯

                                                        No ◯

   Start Date   _____

Evidence of Pneumonia:

Clinical Evidence   Yes ◯

                                                        No ◯

   Date of Assessment   _____

Radiographical Evidence   Yes ◯

                                                        No ◯

   Date of Assessment   _____

Admission to an intensive care unit due to SARS-CoV-2   Yes ◯

                                                        No ●

   Start Date   _____
   End Date   _____

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) **19 Feb 2021 16:47:00**

Generated On: 10 Jun 2021 10:19:18

Generate Next COVID-19 Assessment   Yes ⬭

                                                                          No ⬤

US3912163

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) **15 Mar 2021 18:51:37**

Generated On: 10 Jun 2021 10:19:18

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	12 DEC 2020
Day 5	Yes	14 DEC 2020
Day 7	Yes	16 DEC 2020
Day 9	Yes	18 DEC 2020
Day 14	Yes	23 DEC 2020
Day 21	Yes	31 DEC 2020
Day 28	Yes	5 JAN 2021

US3912163

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) **11 Mar 2021 17:48:51**

Generated On: 10 Jun 2021 10:19:18

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	10 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home ●
	Clinic ○
Folder OID	SICKD1

US3912163

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) **19 Feb 2021 16:47:38**

Generated On: 10 Jun 2021 10:19:18

Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	10 DEC 2020
Time of assessment *(00:00-23:59)*	12:48 (24 HR)
Vital Signs Date and Time (derived)	10 DEC 2020 12:48
Height *(xxx.x)*	71.5 in
Weight *(xxx.x)*	246.2 lb
Temperature *(xxx.x)*	98.6 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	58 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	96 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3912163

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) **19 Feb 2021 16:47:38**

Generated On: 10 Jun 2021 10:19:18

Was the physical examination performed? Yes ●

No ○

Date of examination *(dd MMM yyyy)* 10 DEC 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3912163

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) **16 Mar 2021 21:17:32**

Generated On: 10 Jun 2021 10:19:18

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ●
	No ◯
	NA (COVID-19 Negative) ◯
Date of Collection	10 DEC 2020

US3912163

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) **19 Feb 2021 16:46:59**

Generated On: 10 Jun 2021 10:19:18

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	5 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	SICKD28

US3912163

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) **19 Feb 2021 16:46:59**

Generated On: 10 Jun 2021 10:19:18

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	5 JAN 2021
Time of assessment *(00:00-23:59)*	17:44 (24 HR)
Vital Signs Date and Time (derived)	5 JAN 2021 17:44
Height *(xxx.x)*	ND - Not Done
Weight *(xxx.x)*	ND - Not Done
Temperature *(xxx.x)*	97.0 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	73 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3912163

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) **19 Feb 2021 16:46:59**

Generated On: 10 Jun 2021 10:19:18

Was the physical examination performed?   Yes ●

                                                                 No ○

Date of examination *(dd MMM yyyy)*   5 JAN 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3912163

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) **29 Mar 2021 22:39:21**

Generated On: 10 Jun 2021 10:19:18

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ●
	No ○
	NA (COVID-19 Negative) ○

Date of Collection	5 JAN 2021

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) **29 Mar 2021 22:39:21**

Generated On: 10 Jun 2021 10:19:18

| Was this visit performed? | Yes ● |
| | No ○ |

Visit date (dd MMM yyyy)	05 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

| Folder OID | UNBLND_DECIDE |

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) **09 Mar 2021 19:58:36**

Generated On: 10 Jun 2021 10:19:18

Date of updated informed consent *(dd MMM yyyy)*	05 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ⬤
	No ◯
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ◯
	Amendment 6 or later ⬤
Date of unblinding *(dd MMM yyyy)*	05 FEB 2021
Participant randomization assignment	mRNA-1273 ◯
	Placebo ⬤
Actual Dose 1	mRNA-1273 ◯
	Placebo ⬤
	Not Administered ◯
Actual Dose 2	mRNA-1273 ◯
	Placebo ⬤
	Not Administered ◯
Will participant receive mRNA-1273?	Yes ⬤
	No ◯
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) **09 Mar 2021 19:58:36**

Generated On: 10 Jun 2021 10:19:18

Height	
Weight	
BMI (xxx.x)	

Height	
Weight	
BMI *(xxx.x)*	
Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	26 FEB 2021
Time of assessment *(00:00-23:59)*	14:30 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 14:30
Temperature *(xxx.x)*	98.3 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	65 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	88 mmHg
Diastolic Blood Pressure units	MMHG

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **09 Mar 2021 19:58:36**

Generated On: 10 Jun 2021 10:19:18

Height	
Weight	
BMI *(xxx.x)*	
Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	26 FEB 2021
Time of assessment *(00:00-23:59)*	16:42 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 16:42
Temperature *(xxx.x)*	36.7 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	64 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	92 mmHg
Diastolic Blood Pressure units	MMHG

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) **09 Mar 2021 19:58:36**

Generated On: 10 Jun 2021 10:19:18

| Was the physical examination performed? | Yes ⬤ |
| | No ◯ |

| Date of examination *(dd MMM yyyy)* | 26 FEB 2021 |

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) **09 Mar 2021 19:58:35**

Generated On: 10 Jun 2021 10:19:18

Was study treatment given?	Yes ⬤
	No ◯

If No, reason not given	
Participant declined due to Adverse Event	◯
Physician withheld dose due to Adverse Event	◯
Death	◯
Lost To Follow-Up	◯
Physician Decision	◯
Pregnancy	◯
Protocol Deviation	◯
Study Terminated by Sponsor	◯
Withdrawal of Consent by Participant	◯
Confirmed COVID-19	◯
Other	◯

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	26 FEB 2021
What was the treatment time? *(00:00-23:59)*	15:05 (24 HR)
Treatment Date and Time (derived)	26 FEB 2021 15:05
Which arm was used to give treatment?	Left Arm ⬤
	Right Arm ◯
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **29 Mar 2021 22:39:21**

Generated On: 10 Jun 2021 10:19:18

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	5 FEB 2021
Collection time *(00:00-23:59)*	14:37 (24 HR)
Collection date and time (derived)	5 FEB 2021 14:37

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4)   **15 Mar 2021 18:51:37**

Generated On: 10 Jun 2021 10:19:18

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	5 FEB 2021
Collection time *(00:00 - 23:59)*	14:39
Collection Date and Time (derived)	5 FEB 2021 14:39

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) **09 Mar 2021 19:58:35**

Generated On: 10 Jun 2021 10:19:18

Is the participant continuing to the next visit?   Yes ⬤

                                                          No ◯

Continuing Flag   1

US3912163

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) **09 Mar 2021 19:58:36**

Generated On: 10 Jun 2021 10:19:18

| Was Contact Attempted? | Yes ● |
| | No ○ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 5 MAR 2021 |

| Please select one status for the follow-up contact | Contact Made ● |
| | Contact Not Made ○ |

Comments

If Contact Not Made, please provide Comments _____

US3912163

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) **09 Mar 2021 19:58:36**

Generated On: 10 Jun 2021 10:19:18

Is the participant continuing to the next visit?	Yes ●
	No ○

Continuing Flag	1
OLD29 Placebo Flag	1

US3912163
Folder: OL-D29 (1)
Form: Visit Date
Data signed: (b) (4) **29 Mar 2021 22:39:21**
Generated On: 10 Jun 2021 10:19:18

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	26 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	OLD29

US3912163

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **29 Mar 2021 22:39:21**

Generated On: 10 Jun 2021 10:19:18

Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	26 MAR 2021
Time of assessment *(00:00-23:59)*	14:47 (24 HR)
Vital Signs Date and Time (derived)	26 MAR 2021 14:47
Temperature *(xxx.x)*	97.9 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	70 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	95 mmHg
Diastolic Blood Pressure units	MMHG

Timepoint	Pre-Dose ⚪
	Post-Dose ⚫
Were vital signs assessed?	Yes ⚫
	No ⚪
Date of assessment *(dd MMM yyyy)*	26 MAR 2021
Time of assessment *(00:00-23:59)*	16:35 (24 HR)
Vital Signs Date and Time (derived)	26 MAR 2021 16:35
Temperature *(xxx.x)*	99.1 F
Route of measurement	Oral ⚫
	Axillary ⚪
	Other ⚪
If Other, specify	
Pulse *(xxx)*	55 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	96 mmHg
Diastolic Blood Pressure units	MMHG

Was the physical examination performed?   Yes ●

No ○

Date of examination *(dd MMM yyyy)*   26 MAR 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

Was study treatment given?	Yes ●
	No ○

If No, reason not given	
Participant declined due to Adverse Event	○
Physician withheld dose due to Adverse Event	○
Death	○
Lost To Follow-Up	○
Physician Decision	○
Pregnancy	○
Protocol Deviation	○
Study Terminated by Sponsor	○
Withdrawal of Consent by Participant	○
Confirmed COVID-19	○
Other	○

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	26 MAR 2021
What was the treatment time? *(00:00-23:59)*	15:58 (24 HR)
Treatment Date and Time (derived)	26 MAR 2021 15:58
Which arm was used to give treatment?	Left Arm ●
	Right Arm ○
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3912163
Folder: OL-D29 (1)
Form: Continuing
Data signed: (b) (4) **29 Mar 2021 22:39:21**
Generated On: 10 Jun 2021 10:19:18

Is the participant continuing to the next visit?   Yes ⬤

                                                                 No ◯

Continuing Flag   1

US3912163

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) **05 Apr 2021 00:37:59**

Generated On: 10 Jun 2021 10:19:18

| Was Contact Attempted? | Yes ● |
| | No ○ |

Date of Contact or Contact Attempt *(dd MMM yyyy)*	2 APR 2021
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3912163

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) **05 Apr 2021 00:37:58**

Generated On: 10 Jun 2021 10:19:18

Is the participant continuing to the next visit? Yes ⬤

No ◯

Continuing Flag 1

Was this visit performed?   Yes ◯
                                                             No ◯

Visit date (dd MMM yyyy)   _____

Was visit performed at the participant's home or at the clinic?   Home ◯
                                                                   Clinic ◯

Folder OID   _____

Were vital signs assessed?	Yes ○
	No ○

Date of assessment *(dd MMM yyyy)*	_____
Time of assessment *(00:00-23:59)*	_____
Vital Signs Date and Time (derived)	_____
Temperature *(xxx.x)*	_____

Route of measurement	Oral ○
	Axillary ○
	Other ○

If Other, specify	_____
Pulse *(xxx)*	_____
Pulse units	_____
Respiratory Rate *(xxx)*	_____
Respiratory Rate units	_____
Systolic Blood Pressure *(xxx)*	_____
Systolic Blood Pressure units	_____
Diastolic Blood Pressure *(xxx)*	_____
Diastolic Blood Pressure units	_____
Height (derived)	_____
Weight (derived)	_____

Was the physical examination performed?   Yes ◯

                                                                                               No ◯

Date of examination *(dd MMM yyyy)*

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

FDA-CBER-2022-1614-3508585

Was the sample collected?   Yes ◯

                                                                             No ◯

Collection date *(dd MMM yyyy)*	
Collection time *(00:00-23:59)*	
Collection date and time (derived)	

US3912163

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) **19 Feb 2021 16:46:59**

Generated On: 10 Jun 2021 10:19:18

Did the participant experience any adverse events?   Yes ●

                                                                      No ○

If Yes, enter details on the Adverse Events form.

AEID	
Adverse event	DIARRHEA

Was this a medically-attended AE? Yes ◯ No ⬤

Was this a Solicited Adverse Reaction? Yes ◯ No ⬤

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes ◯ No ⬤

Start date *(dd MMM yyyy)*	15 SEP 2020
Start time *(00:00-23:59)*	17:00 (24 HR)
AE start date and time (derived)	15 SEP 2020 17:00

Ongoing? Yes ◯ No ⬤

If not Ongoing, end date *(dd MMM yyyy)*	16 SEP 2020
End time *(00:00-23:59)*	18:00 (24 HR)
AE End Date and Time (derived)	16 SEP 2020 18:00

Severity Grade 1/Mild ◯ Grade 2/Moderate ⬤ Grade 3/Severe ◯ Grade 4 ◯

Is the adverse event serious? Yes ◯ No ⬤

AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	

Admitted to ICU? Yes ◯ No ◯ Unknown ◯

Number of Days in ICU	

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product
- Not Related ◯
- Related ⬤
- Not Applicable ◯

Relationship to Study Procedure
- Not Related ⬤
- Related ◯
- Not Applicable ◯

Action taken with investigational product
- None ⬤
- Dose Delayed ◯
- Investigational Product Withdrawn ◯
- Not Applicable ◯

Other action taken (check all that apply)

None	True
Concomitant Medication	False
Concomitant Procedure	False

Outcome
- Fatal ◯
- Not Recovered/Not Resolved ◯
- Recovered/Resolved ⬤
- Recovered/Resolved with Sequelae ◯
- Recovering/Resolving ◯
- Unknown ◯

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3912163

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) **11 Mar 2021 17:48:50**

Generated On: 10 Jun 2021 10:19:18

AEID	
Adverse event	WORSENING OF HYPERTENSION
Was this a medically-attended AE?	Yes ◯
	No ⬤
Was this a Solicited Adverse Reaction?	Yes ◯
	No ⬤
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ◯
	No ⬤
Start date *(dd MMM yyyy)*	13 OCT 2020
Start time *(00:00-23:59)*	09:55 (24 HR)
AE start date and time (derived)	13 OCT 2020 09:55
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, end date *(dd MMM yyyy)*	13 OCT 2020
End time *(00:00-23:59)*	10:07 (24 HR)
AE End Date and Time (derived)	13 OCT 2020 10:07
Severity	Grade 1/Mild ◯
	Grade 2/Moderate ◯
	Grade 3/Severe ⬤
	Grade 4 ◯
Is the adverse event serious?	Yes ◯
	No ⬤

AE is serious due To (check all that apply)

Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ◯
	No ◯
	Unknown ◯

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	
	Not Related ⬤
	Related ◯
	Not Applicable ◯

Relationship to Study Procedure	
	Not Related ⬤
	Related ◯
	Not Applicable ◯

Action taken with investigational product	
	None ◯
	Dose Delayed ◯
	Investigational Product Withdrawn ◯
	Not Applicable ⬤

Other action taken (check all that apply)

None	True
Concomitant Medication	False
Concomitant Procedure	False

Outcome	
	Fatal ◯
	Not Recovered/Not Resolved ◯
	Recovered/Resolved ⬤
	Recovered/Resolved with Sequelae ◯
	Recovering/Resolving ◯
	Unknown ◯

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3912163

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) **11 Mar 2021 17:48:50**

Generated On: 10 Jun 2021 10:19:18

AEID	USA-US211-2020-MRNA-1273-P30 1000008
Adverse event	SYMPTOMATIC COVID-19 (SYMPTOMS OF BODY ACHES,NASAL CONGESTION,COUGH)

Was this a medically-attended AE?　　Yes ⬤　No ◯

Was this a Solicited Adverse Reaction?　　Yes ◯　No ⬤

Is this event a confirmed diagnosis of Symptomatic Covid-19?　　Yes ⬤　No ◯

Start date *(dd MMM yyyy)*	4 DEC 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing?　　Yes ◯　No ⬤

If not Ongoing, end date *(dd MMM yyyy)*	22 DEC 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

Severity　　Grade 1/Mild ⬤　Grade 2/Moderate ◯　Grade 3/Severe ◯　Grade 4 ◯

Is the adverse event serious?　　Yes ◯　No ⬤

AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	

Admitted to ICU?　　Yes ◯

	No ◯
	Unknown ◯
Number of Days in ICU	_____
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ⬤
	Related ◯
	Not Applicable ◯
Relationship to Study Procedure	Not Related ⬤
	Related ◯
	Not Applicable ◯
Action taken with investigational product	None ◯
	Dose Delayed ◯
	Investigational Product Withdrawn ◯
	Not Applicable ⬤

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ◯
	Not Recovered/Not Resolved ◯
	Recovered/Resolved ⬤
	Recovered/Resolved with Sequelae ◯
	Recovering/Resolving ◯
	Unknown ◯
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	_____
Narrative	_____
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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US3912163

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) **11 Mar 2021 17:48:50**

Generated On: 10 Jun 2021 10:19:18

AEID	
Adverse event	LOOSE STOOLS
Was this a medically-attended AE?	Yes ⬤ No
	No ⬤
Was this a Solicited Adverse Reaction?	Yes ◯
	No ⬤
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ◯
	No ⬤
Start date *(dd MMM yyyy)*	08 DEC 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, end date *(dd MMM yyyy)*	08 DEC 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ⬤
	Grade 2/Moderate ◯
	Grade 3/Severe ◯
	Grade 4 ◯
Is the adverse event serious?	Yes ◯
	No ⬤
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ◯
	No ◯
	Unknown ◯
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) **11 Mar 2021 17:48:50**

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	
	Not Related ⬤
	Related ◯
	Not Applicable ◯

Relationship to Study Procedure	
	Not Related ⬤
	Related ◯
	Not Applicable ◯

Action taken with investigational product	
	None ◯
	Dose Delayed ◯
	Investigational Product Withdrawn ◯
	Not Applicable ⬤

Other action taken (check all that apply)

None	True
Concomitant Medication	False
Concomitant Procedure	False

Outcome	
	Fatal ◯
	Not Recovered/Not Resolved ◯
	Recovered/Resolved ⬤
	Recovered/Resolved with Sequelae ◯
	Recovering/Resolving ◯
	Unknown ◯

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) **11 Mar 2021 17:48:50**

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AEID	USA-US211-2021-MRNA-1273-P30 1000002
Adverse event	NSTEMI-NON ST-ELEVATION MYOCARDIAL INFARCTION

Was this a medically-attended AE? Yes ● No ○

Was this a Solicited Adverse Reaction? Yes ○ No ●

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes ○ No ●

Start date *(dd MMM yyyy)*	1 FEB 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing? Yes ○ No ●

If not Ongoing, end date *(dd MMM yyyy)*	2 FEB 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

Severity Grade 1/Mild ○ Grade 2/Moderate ○ Grade 3/Severe ● Grade 4 ○

Is the adverse event serious? Yes ● No ○

AE is serious due To (check all that apply)

Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	1 FEB 2021
Hospital Discharge Date *(dd MMM yyyy)*	2 FEB 2021

Admitted to ICU? Yes ○ No ● Unknown ○

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	
	Not Related ⬤
	Related ◯
	Not Applicable ◯

Relationship to Study Procedure	
	Not Related ⬤
	Related ◯
	Not Applicable ◯

Action taken with investigational product	
	None ◯
	Dose Delayed ◯
	Investigational Product Withdrawn ◯
	Not Applicable ⬤

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	True

Outcome	
	Fatal ◯
	Not Recovered/Not Resolved ◯
	Recovered/Resolved ⬤
	Recovered/Resolved with Sequelae ◯
	Recovering/Resolving ◯
	Unknown ◯

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative

SUBJECT UNDERWENT
ANGIOPLASTY AND STENT
PLACEMENT ON 01FEB2021.

SUBJECT EXPERIENCED NEW
ONSET OF CHEST PAIN THE
MORNING OF 01FEB2021; HE
PRESENTED TO FREE
STANDING ER FOR
EVALUATION AND DUE TO
NOTED INCREASE IN CARDIAC
ENZYMES HE WAS
TRANSFERRED TO ER WITH
HIGHER LEVEL OF CARE. UPON
PRESENTATION TO 2ND ER, HE
WAS TAKEN EMERGENTLY TO
THE CATH LAB WHERE HE
UNDERWENT CARDIAC
CATHETERIZATION. THAT
PROCEDURE REVEALED
SIGNIFICANT CORONARY
ARTERY DISEASE OF THE LEFT
CIRCUMFLEX (70% STENOSIS)
WITH APPEARANCE OF
ULCERATED PLAQUE;
SUCCESSFUL PCI OF THE MID
LEFT CIRCUMFLEX ARTERY
USING 2.25 X 22MM RESOLUTE
ONXY DRUG ELUDING STENT
WITH IMPROVEMENT IN
STENOSIS SEVERITY FROM 70%
WITH ULCERATED PLAQUE TO
0% RESIDUAL STENOSIS AND
TIMI 3 FLOW POST
INTERVENTION.

Serious Adverse Event Derived (CSA Programming Field Ony)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

AEID	
Adverse event	HYPERLIPIDEMIA
Was this a medically-attended AE?	Yes ●
	No ○
Was this a Solicited Adverse Reaction?	Yes ○
	No ●
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ○
	No ●
Start date *(dd MMM yyyy)*	1 FEB 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ●
	No ○
If not Ongoing, end date *(dd MMM yyyy)*	
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ○
	Grade 2/Moderate ●
	Grade 3/Severe ○
	Grade 4 ○
Is the adverse event serious?	Yes ○
	No ●
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ○
	No ○
	Unknown ○
Number of Days in ICU	

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	
	Not Related ●
	Related ○
	Not Applicable ○

Relationship to Study Procedure	
	Not Related ●
	Related ○
	Not Applicable ○

Action taken with investigational product	
	None ○
	Dose Delayed ○
	Investigational Product Withdrawn ○
	Not Applicable ●

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome	
	Fatal ○
	Not Recovered/Not Resolved ○
	Recovered/Resolved ○
	Recovered/Resolved with Sequelae ○
	Recovering/Resolving ●
	Unknown ○

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) **19 Feb 2021 16:46:59**

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Were any prior/concomitant medications and/or vaccinations taken?   Yes ●

No ◯

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

Name of Medication	METOPROLOL TARTRATE

Prophylaxis

Yes ○
No ●

Indication	HYPERTENSION
Dose per administration	50

Dose unit

mg ●
ug ○
mL ○
g ○
IU ○
tablet ○
capsule ○
puff ○
Other ○

If dose unit is Other, specify _____

Frequency

once daily ●
twice daily ○
three times daily ○
four times daily ○
every other day ○
every week ○
every month ○
as needed ○
once ○
unknown ○
other ○

If frequency is Other, specify _____

Route of administration

Oral ●
Topical ○
Subcutaneous ○
Transdermal ○
Intraocular ○

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN SEP 2018
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Name of Medication	PEPTO BISMOL FOR DIARRHEA

Prophylaxis	Yes ⚪
	No ⚫

Indication	DIARRHEA

Dose per administration	60

Dose unit	mg ⚪
	ug ⚪
	mL ⚫
	g ⚪
	IU ⚪
	tablet ⚪
	capsule ⚪
	puff ⚪
	Other ⚪

If dose unit is Other, specify	

Frequency	once daily ⚪
	twice daily ⚪
	three times daily ⚪
	four times daily ⚪
	every other day ⚪
	every week ⚪
	every month ⚪
	as needed ⚪
	once ⚫
	unknown ⚪
	other ⚪

If frequency is Other, specify	

Route of administration	Oral ⚫
	Topical ⚪
	Subcutaneous ⚪
	Transdermal ⚪
	Intraocular ⚪

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	16 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	16 DEC 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Name of Medication	IBUPROFEN

Prophylaxis

Yes ◯
No ⬤

Indication	BODY ACHES
Dose per administration	200

Dose unit

mg ⬤
ug ◯
mL ◯
g ◯
IU ◯
tablet ◯
capsule ◯
puff ◯
Other ◯

If dose unit is Other, specify _____

Frequency

once daily ◯
twice daily ◯
three times daily ◯
four times daily ◯
every other day ◯
every week ◯
every month ◯
as needed ⬤
once ◯
unknown ◯
other ◯

If frequency is Other, specify _____

Route of administration

Oral ⬤
Topical ◯
Subcutaneous ◯
Transdermal ◯
Intraocular ◯

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	7 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	21 DEC 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) **11 Mar 2021 17:48:51**

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Name of Medication	NYQUIL COLD & FLU

Prophylaxis

Yes ◯
No ⬤

Indication	NASAL CONGESTION
Dose per administration	30

Dose unit

mg ◯
ug ◯
mL ⬤
g ◯
IU ◯
tablet ◯
capsule ◯
puff ◯
Other ◯

If dose unit is Other, specify _____

Frequency

once daily ◯
twice daily ◯
three times daily ◯
four times daily ◯
every other day ◯
every week ◯
every month ◯
as needed ⬤
once ◯
unknown ◯
other ◯

If frequency is Other, specify _____

Route of administration

Oral ⬤
Topical ◯
Subcutaneous ◯
Transdermal ◯
Intraocular ◯

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	7 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	21 DEC 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: [(b) (4)] **11 Mar 2021 17:48:51**

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Name of Medication	GUAIFENESIN
Prophylaxis	Yes ◯
	No ⬤
Indication	COUGH
Dose per administration	400
Dose unit	mg ⬤
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ◯
If dose unit is Other, specify	
Frequency	once daily ◯
	twice daily ◯
	three times daily ◯
	four times daily ◯
	every other day ◯
	every week ◯
	every month ◯
	as needed ⬤
	once ◯
	unknown ◯
	other ◯
If frequency is Other, specify	
Route of administration	Oral ⬤
	Topical ◯
	Subcutaneous ◯
	Transdermal ◯
	Intraocular ◯

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	7 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	10 DEC 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) **11 Mar 2021 17:48:51**

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Name of Medication	AZELASTINE HCl NASAL SOLUTION

Prophylaxis

Yes ⭘
No ⬤

Indication	NASAL CONGESTION
Dose per administration	137

Dose unit

mg ⭘
ug ⬤
mL ⭘
g ⭘
IU ⭘
tablet ⭘
capsule ⭘
puff ⭘
Other ⭘

If dose unit is Other, specify _____

Frequency

once daily ⭘
twice daily ⬤
three times daily ⭘
four times daily ⭘
every other day ⭘
every week ⭘
every month ⭘
as needed ⭘
once ⭘
unknown ⭘
other ⭘

If frequency is Other, specify _____

Route of administration

Oral ⭘
Topical ⭘
Subcutaneous ⭘
Transdermal ⭘

	Intraocular ◯
	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ⬤
	Vaginal ◯
	Rectal ◯
	Intravenous ◯
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	7 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	21 DEC 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) **11 Mar 2021 17:48:51**

Generated On: 10 Jun 2021 10:19:18

Name of Medication	ZINC
Prophylaxis	Yes ●
	No ○
Indication	HEALTH SUPPLEMENT
Dose per administration	250
Dose unit	mg ●
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ○
If dose unit is Other, specify	
Frequency	once daily ○
	twice daily ●
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ○
	once ○
	unknown ○
	other ○
If frequency is Other, specify	
Route of administration	Oral ●
	Topical ○
	Subcutaneous ○
	Transdermal ○
	Intraocular ○

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	7 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) **11 Mar 2021 17:48:51**

Generated On: 10 Jun 2021 10:19:18

Name of Medication	VITAMIN C
Prophylaxis	Yes ●
	No ○
Indication	HEALTH SUPPLEMENT
Dose per administration	1000
Dose unit	mg ●
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ○
If dose unit is Other, specify	
Frequency	once daily ○
	twice daily ●
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ○
	once ○
	unknown ○
	other ○
If frequency is Other, specify	
Route of administration	Oral ●
	Topical ○
	Subcutaneous ○
	Transdermal ○
	Intraocular ○

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EAB) (1725)

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	7 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

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Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Data signed: (b) (4) **11 Mar 2021 17:48:51**
Generated On: 10 Jun 2021 10:19:18

Name of Medication	TYLENOL COLD & FLU (ACETAMINOPHEN 325 MG; DEXTROMETHORPHAN 10 MG; GUAIFENESIN 200 MG; PHENYLEPHRINE HCI 5 MG)

Prophylaxis

Yes ◯
No ⬤

Indication	NASAL CONGESTION
Dose per administration	1

Dose unit

mg ◯
ug ◯
mL ◯
g ◯
IU ◯
tablet ◯
capsule ⬤
puff ◯
Other ◯

If dose unit is Other, specify

Frequency

once daily ◯
twice daily ⬤
three times daily ◯
four times daily ◯
every other day ◯
every week ◯
every month ◯
as needed ◯
once ◯
unknown ◯
other ◯

If frequency is Other, specify

Route of administration

Oral ⬤
Topical ◯

Subcutaneous	◯
Transdermal	◯
Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	7 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	8 DEC 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

FDA-CBER-2022-1614-3508619

Name of Medication	MINERAL SUPPLEMENT (CALCIUM, MAGNESIUM, AND ZINC)

Prophylaxis

Yes ⬤
No ◯

Indication	HEALTH SUPPLEMENT
Dose per administration	1

Dose unit

mg ◯
ug ◯
mL ◯
g ◯
IU ◯
tablet ⬤
capsule ◯
puff ◯
Other ◯

If dose unit is Other, specify

Frequency

once daily ◯
twice daily ⬤
three times daily ◯
four times daily ◯
every other day ◯
every week ◯
every month ◯
as needed ◯
once ◯
unknown ◯
other ◯

If frequency is Other, specify

Route of administration

Oral ⬤
Topical ◯
Subcutaneous ◯
Transdermal ◯

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Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	7 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) **11 Mar 2021 17:48:51**

Generated On: 10 Jun 2021 10:19:18

Name of Medication	ROSUVASTATIN

Prophylaxis	
Yes	○
No	●

Indication	HYPERLIPIDEMIA
Dose per administration	20

Dose unit	
mg	●
ug	○
mL	○
g	○
IU	○
tablet	○
capsule	○
puff	○
Other	○

If dose unit is Other, specify

Frequency	
once daily	○
twice daily	●
three times daily	○
four times daily	○
every other day	○
every week	○
every month	○
as needed	○
once	○
unknown	○
other	○

If frequency is Other, specify

Route of administration	
Oral	●
Topical	○
Subcutaneous	○
Transdermal	○
Intraocular	○

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	1 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) **11 Mar 2021 17:48:51**

Generated On: 10 Jun 2021 10:19:18

Name of Medication	ASPIRIN
Prophylaxis	Yes ◯
	No ⬤

Indication	MYOCARDIAL INFARCTION
Dose per administration	81

Dose unit
- mg ⬤
- ug ◯
- mL ◯
- g ◯
- IU ◯
- tablet ◯
- capsule ◯
- puff ◯
- Other ◯

If dose unit is Other, specify _____

Frequency
- once daily ⬤
- twice daily ◯
- three times daily ◯
- four times daily ◯
- every other day ◯
- every week ◯
- every month ◯
- as needed ◯
- once ◯
- unknown ◯
- other ◯

If frequency is Other, specify _____

Route of administration
- Oral ⬤
- Topical ◯
- Subcutaneous ◯
- Transdermal ◯
- Intraocular ◯

PRODUCTION RELEASE (v12.003
EAB) (1725)

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	1 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) **11 Mar 2021 17:48:51**

Generated On: 10 Jun 2021 10:19:18

Name of Medication	BRILINTA
Prophylaxis	Yes ◯
	No ⬤
Indication	MYOCARDIAL INFARCTION
Dose per administration	90
Dose unit	mg ⬤
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ◯
If dose unit is Other, specify	
Frequency	once daily ◯
	twice daily ⬤
	three times daily ◯
	four times daily ◯
	every other day ◯
	every week ◯
	every month ◯
	as needed ◯
	once ◯
	unknown ◯
	other ◯
If frequency is Other, specify	
Route of administration	Oral ⬤
	Topical ◯
	Subcutaneous ◯
	Transdermal ◯
	Intraocular ◯

US3912163

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Data signed: (b) (4) **11 Mar 2021 17:48:51**
Generated On: 10 Jun 2021 10:19:18

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	1 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) **11 Mar 2021 17:48:51**

Generated On: 10 Jun 2021 10:19:18

Name of Medication	NITROGLYCERIN
Prophylaxis	Yes ◯
	No ●

Indication	MYOCARDIAL INFARCTION
Dose per administration	0.4

Dose unit	
	mg ●
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ◯

If dose unit is Other, specify _____

Frequency	
	once daily ◯
	twice daily ◯
	three times daily ◯
	four times daily ◯
	every other day ◯
	every week ◯
	every month ◯
	as needed ●
	once ◯
	unknown ◯
	other ◯

If frequency is Other, specify _____

Route of administration	
	Oral ◯
	Topical ◯
	Subcutaneous ◯
	Transdermal ◯
	Intraocular ◯

PRODUCTION RELEASE (v12.003
EAB) (1725)

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	⬤

If route of administration is Other, specify	SUBLINGUAL
Start date *(dd MMM yyyy)*	1 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯

If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤

Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Name of Medication _____

Prophylaxis   Yes ◯
                                                   No ◯

Indication _____

Dose per administration _____

Dose unit   mg ◯
                                                   ug ◯
                                                   mL ◯
                                                    g ◯
                                                   IU ◯
                                               tablet ◯
                                              capsule ◯
                                                 puff ◯
                                                Other ◯

If dose unit is Other, specify _____

Frequency   once daily ◯
                                             twice daily ◯
                                        three times daily ◯
                                         four times daily ◯
                                         every other day ◯
                                              every week ◯
                                             every month ◯
                                               as needed ◯
                                                   once ◯
                                                unknown ◯
                                                  other ◯

If frequency is Other, specify _____

Route of administration   Oral ◯
                                                Topical ◯
                                           Subcutaneous ◯
                                            Transdermal ◯
                                             Intraocular ◯

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	
Start date completely unknown	
Ongoing?	Yes ◯
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ◯
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

US3912163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: [(b) (4)] **19 Feb 2021 16:46:59**

Generated On: 10 Jun 2021 10:19:18

Were any concomitant procedures performed?   Yes ●

                                                                    No ○

If yes, please complete Concomitant Procedures form.

US3912163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: ▓ (b) (4) ▓ **19 Feb 2021 16:46:59**

Generated On: 10 Jun 2021 10:19:18

Procedure/Surgery date (*dd MMM yyyy*)	Procedure/Surgery	Indication	If indication is Other, specify
1 FEB 2021	STENT PLACEMENT	Adverse Event	
1 FEB 2021	ANGIOPLASTY	Adverse Event	

Date of study discontinuation/completion *(dd MMM yyyy)*	

Reason for discontinuation	
	AE (specify) ◯
	SAE (specify) ◯
	Complete ◯
	Death ◯
	Lost To Follow-up ◯
	Physician decision (specify) ◯
	Pregnancy ◯
	Protocol deviation (specify) ◯
	Study Terminated By Sponsor ◯
	Withdrawal of consent by participant (specify) ◯
	Other ◯

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	

If reason for discontinuation is Death, main cause of death	
	Adverse event ◯
	Unknown ◯
	Other ◯

If main cause of death is Other, specify	
Date of death *(dd MMM yyyy)*	

Was autopsy performed?	
	Yes ◯
	No ◯
	Unknown ◯

FDA-CBER-2022-1614-3508634

US3912163

Folder: SAE USA-US211-2020-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: [(b) (4)] **12 Mar 2021 19:13:20**

Generated On: 10 Jun 2021 10:19:18

SAEID	USA-US211-2020-MRNA-1273-P30 1000008
Serious	Yes ◯ No ⬤
Death	Yes ◯ No ⬤
Life threatening	Yes ◯ No ⬤
Requires inpatient or prolongation of existing Hospitalization	Yes ◯ No ⬤
Persistent or significant disability or incapacity	Yes ◯ No ⬤
Congenital anomaly or birth defect	Yes ◯ No ⬤
Other medically important event	Yes ◯ No ⬤
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3912163

Folder: SAE USA-US211-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) **12 Mar 2021 19:13:20**

Generated On: 10 Jun 2021 10:19:18

SAEID	USA-US211-2020-MRNA-1273-P30 1000008
Serious	Yes ○ No ●
Death	Yes ○ No ●
Life threatening	Yes ○ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ○ No ●
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	17/DEC/2020 18:15
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3912163

Folder: SAE USA-US211-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) **12 Mar 2021 19:13:20**

Generated On: 10 Jun 2021 10:19:18

SAEID	USA-US211-2020-MRNA-1273-P30 1000008
Serious	Yes ◯ No ⬤
Death	Yes ◯ No ⬤
Life threatening	Yes ◯ No ⬤
Requires inpatient or prolongation of existing Hospitalization	Yes ◯ No ⬤
Persistent or significant disability or incapacity	Yes ◯ No ⬤
Congenital anomaly or birth defect	Yes ◯ No ⬤
Other medically important event	Yes ◯ No ⬤
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	23/DEC/2020 13:55
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form (3)
Data signed: (b) (4) **12 Mar 2021 19:13:20**
Generated On: 10 Jun 2021 10:19:18

SAEID	USA-US211-2020-MRNA-1273-P30 1000008
Serious	Yes ◯ No ⬤
Death	Yes ◯ No ⬤
Life threatening	Yes ◯ No ⬤
Requires inpatient or prolongation of existing Hospitalization	Yes ◯ No ⬤
Persistent or significant disability or incapacity	Yes ◯ No ⬤
Congenital anomaly or birth defect	Yes ◯ No ⬤
Other medically important event	Yes ◯ No ⬤
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	11/JAN/2021 14:52
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form (4)
Data signed: (b) (4) **12 Mar 2021 19:13:20**
Generated On: 10 Jun 2021 10:19:18

SAEID	USA-US211-2020-MRNA-1273-P30 1000008
Serious	Yes ⬜ No 🔘
Death	Yes ⬜ No 🔘
Life threatening	Yes ⬜ No 🔘
Requires inpatient or prolongation of existing Hospitalization	Yes ⬜ No 🔘
Persistent or significant disability or incapacity	Yes ⬜ No 🔘
Congenital anomaly or birth defect	Yes ⬜ No 🔘
Other medically important event	Yes ⬜ No 🔘
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	11/MAR/2021 13:47
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3912163

Folder: SAE USA-US211-2021-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: ▨ (b) (4) ▨ **12 Mar 2021 19:13:20**

Generated On: 10 Jun 2021 10:19:18

SAEID	USA-US211-2021-MRNA-1273-P30 1000002
Serious	Yes ●
	No ○
Death	Yes ○
	No ●
Life threatening	Yes ●
	No ○
Requires inpatient or prolongation of existing Hospitalization	Yes ●
	No ○
Persistent or significant disability or incapacity	Yes ○
	No ●
Congenital anomaly or birth defect	Yes ○
	No ●
Other medically important event	Yes ○
	No ●
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3912163

Folder: SAE USA-US211-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: ▨ (b) (4) ▨ **12 Mar 2021 19:13:20**

Generated On: 10 Jun 2021 10:19:18

SAEID	USA-US211-2021-MRNA-1273-P30 1000002
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ● No ○
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	05/FEB/2021 08:01
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form (2)
Data signed: [(b) (4)] **12 Mar 2021 19:13:20**
Generated On: 10 Jun 2021 10:19:18

SAEID	USA-US211-2021-MRNA-1273-P30 1000002
Serious	Yes ⬤ No ◯
Death	Yes ◯ No ⬤
Life threatening	Yes ⬤ No ◯
Requires inpatient or prolongation of existing Hospitalization	Yes ⬤ No ◯
Persistent or significant disability or incapacity	Yes ◯ No ⬤
Congenital anomaly or birth defect	Yes ◯ No ⬤
Other medically important event	Yes ◯ No ⬤
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	08/FEB/2021 10:12
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3912163

Folder: SAE USA-US211-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) **12 Mar 2021 19:13:20**

Generated On: 10 Jun 2021 10:19:18

SAEID	USA-US211-2021-MRNA-1273-P30 1000002
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ● No ○
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	11/FEB/2021 14:57
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3912163

Folder: SAE USA-US211-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) **12 Mar 2021 19:13:20**

Generated On: 10 Jun 2021 10:19:18

SAEID	USA-US211-2021-MRNA-1273-P30 1000002
Serious	Yes ●
	No ○
Death	Yes ○
	No ●
Life threatening	Yes ●
	No ○
Requires inpatient or prolongation of existing Hospitalization	Yes ●
	No ○
Persistent or significant disability or incapacity	Yes ○
	No ●
Congenital anomaly or birth defect	Yes ○
	No ●
Other medically important event	Yes ○
	No ●
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	12/FEB/2021 09:05
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3912163 (Prod: Synexus - Optimal Research - Austin)

US3912163

Form: Participant Creation

Generated On: 10 Jun 2021 10:19:18

Participant ID

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
User entered 'US3912163'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 15:09:20

US3912163
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 10:19:18

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:38:59

US3912163
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 10:19:18

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '15 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 15:09:21

US3912163

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:19:18

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Clinic (Clinic)'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:38:59

US3912163

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:19:18

Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User entered 'SCRN'	System	15 Sep 2020 16:38:59

US3912163

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:18

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered (b) (6) 1977'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 15:09:22

US3912163

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:18

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '43'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:44:04

Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User entered 'YEARS'	System	15 Sep 2020 16:44:04

US3912163
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:19:18
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User entered '43'	System	15 Sep 2020 16:39:16

US3912163
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:19:18
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Male (M)'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:44:04

US3912163

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:18

Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:44:04

US3912163
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:19:18
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '0'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:44:04

US3912163
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:19:18
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '0'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:44:04

US3912163

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:18

Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '0'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:44:04

US3912163

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:18

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '0'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:44:04

US3912163

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:18

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '0'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:44:04

US3912163
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:19:18
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '1'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:44:04

US3912163

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:19:18

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Arabic'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:44:04

US3912163
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:19:18
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '0'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:44:04

US3912163
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:19:18
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '0'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:44:04

US3912163

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:19:18

Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '15 Sep 2020'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:39:16

FDA-CBER-2022-1614-3508666

US3912163

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:19:18

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User entered 'Sep 2020'	System	15 Sep 2020 16:39:16

US3912163

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:19:18

Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User entered '2020'	System	15 Sep 2020 16:39:16

US3912163

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:19:18

Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 16:39:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Sep 2020 16:39:25
User entered 'Amendment 3 (3)' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:39:25
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 16:39:16
User entered empty.	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:39:16

US3912163

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:19:18

Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:39:16

US3912163

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:19:18

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered empty.	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:39:16

Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 10:19:18
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered empty.	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:39:16

Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:39:16

US3912163
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 10:19:18
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 15:09:21

US3912163
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 10:19:18
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User entered '1'	System	15 Sep 2020 16:39:29

US3912163

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:19:18

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:39:29

US3912163

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:19:18

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:45:13

US3912163

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:19:18

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 16:47:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 16:47:55
Data point term sent to Coder	System	15 Sep 2020 16:46:38
User entered 'Hypertension'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:45:37

US3912163
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 10:19:18
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'UN Sep 2018'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:45:37

US3912163

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:19:18

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '0'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:45:37

US3912163

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:19:18

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:45:37

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:19:18

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered empty.	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:45:37

US3912163

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:19:18

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '0'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:45:37

US3912163

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:19:18

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User entered 'Sep 2018'	System	15 Sep 2020 16:45:37

US3912163

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:19:18

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User entered '2018'	System	15 Sep 2020 16:45:37

US3912163

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:19:18

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User entered empty.	System	15 Sep 2020 16:45:37

US3912163
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 10:19:18

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User entered empty.	System	15 Sep 2020 16:45:37

US3912163

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:18

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:46:35

US3912163
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '15 Sep 2020'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:46:35

US3912163

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:18

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '10:16'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:46:35

US3912163

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:18

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User entered '15 Sep 2020 10:16'	System	15 Sep 2020 16:46:35

US3912163
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '71.5' in	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:46:35
DataPoint set to visible.	System	15 Sep 2020 16:39:29

US3912163
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '264' lb	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:46:35
DataPoint set to visible.	System	15 Sep 2020 16:39:29

US3912163
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User entered '36.38327'	System	15 Sep 2020 16:46:35
DataPoint set to visible.	System	15 Sep 2020 16:39:29

US3912163

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:18

BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User entered 'kg/m2'	System	15 Sep 2020 16:46:35
DataPoint set to visible.	System	15 Sep 2020 16:39:29

US3912163

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:18

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered missing code ND - Not Done.	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:46:35

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered empty.	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:46:35

US3912163
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered empty.	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:46:35

US3912163
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered missing code ND - Not Done.	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:46:35

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User entered 'bpm'	System	15 Sep 2020 16:46:35

US3912163
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered missing code ND - Not Done.	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:46:35

US3912163
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User entered 'breaths/min'	System	15 Sep 2020 16:46:35

US3912163
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered missing code ND - Not Done.	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:46:35

US3912163
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User entered 'mmHg'	System	15 Sep 2020 16:46:35

US3912163
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered missing code ND - Not Done.	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:46:35

US3912163
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User entered 'mmHg'	System	15 Sep 2020 16:46:35

US3912163
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57

Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57

US3912163

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:19:18

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:46:44

US3912163

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:19:18

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '15 Sep 2020'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:46:44

US3912163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:18

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:48:06

US3912163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:18

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:48:06

US3912163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:18

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:48:06

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Folder: Screening

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Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:48:06

FDA-CBER-2022-1614-3508714

US3912163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:18

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:48:06

US3912163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:18

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:48:06

US3912163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:18

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:48:06

US3912163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:18

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:48:06

US3912163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:18

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:48:06

US3912163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:18

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:48:06

US3912163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:18

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:48:06

US3912163
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:19:18
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:48:06

US3912163
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:19:18
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered empty.	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:48:06

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:18

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '0'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:48:06

US3912163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:18

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '0'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:48:06

US3912163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:18

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '0'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:48:06

US3912163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:18

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '0'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:48:06

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:18

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '1'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:48:06

US3912163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:18

Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '0'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:48:06

US3912163
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:19:18
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '0'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:48:06

US3912163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:19:18

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:46:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered empty.	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:48:06

US3912163

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:19:18

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:48:19

US3912163
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 10:19:18

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '15 Sep 2020'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:48:19

US3912163

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:19:18

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Clinic (Clinic)'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:48:19

US3912163
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 10:19:18
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered 'VISIT1'	System	15 Sep 2020 16:48:19

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:19:18

What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
User entered '15 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 15:54:40

Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 10:19:18

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '113655'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 15:54:40

US3912163

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:19:18

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 15:54:40

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:19:18

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'No (N)'	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:00:21

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:19:18

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'No (N)'	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:00:21

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:19:18

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'No (N)'	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:00:21

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:19:18

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'No (N)'	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:00:21

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:19:18

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'No (N)'	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:00:21

US3912163

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:19:18

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 13:53:41
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:15:08
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:15:07

US3912163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:19:18

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 07:13:23
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1.' answered with 'corrected' (Site from DM).	Timothy Vachris (b) (4) (b) (4)	05 Oct 2020 13:03:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Timothy Vachris (b) (4) (b) (4)	05 Oct 2020 13:03:13
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 16:15:57
User entered '71.5' in	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:04:39

US3912163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 10:19:18
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Timothy Vachris (b) (4) (b) (4)	05 Oct 2020 13:03:13
User entered '246.0' lb	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:04:39

US3912163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 10:19:18
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 07:13:23
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1.' answered with 'corrected' (Site from DM).	Timothy Vachris (b) (4) (b) (4)	05 Oct 2020 13:03:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Timothy Vachris (b) (4) (b) (4)	05 Oct 2020 13:03:13
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 16:15:57
User entered '71.5' in	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:04:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:19:18

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Timothy Vachris (b) (4) (b) (4)	05 Oct 2020 13:03:13
User entered '246.0' lb	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:04:39

US3912163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:19:18
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User accepted default value 'Pre-Dose (PREDOSE)'	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:04:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:04:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '15 Sep 2020'	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:04:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '10:16'	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:04:39

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered '15 Sep 2020 10:16'	System	16 Sep 2020 20:04:39

US3912163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '37.0' C	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:04:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Oral (Oral)'	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:04:39

US3912163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:19:18
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered empty.	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:04:39

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '60'	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:04:39

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered 'bpm'	System	16 Sep 2020 20:04:39

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '14'	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:04:39

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered 'breaths/min'	System	16 Sep 2020 20:04:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '126'	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:04:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered 'mmHg'	System	16 Sep 2020 20:04:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '78'	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:04:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered 'mmHg'	System	16 Sep 2020 20:04:39

US3912163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:19:18

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 07:13:23
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1.' answered with 'corrected' (Site from DM).	Timothy Vachris (b) (4) (b) (4)	05 Oct 2020 13:03:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Timothy Vachris (b) (4) (b) (4)	05 Oct 2020 13:03:13
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 16:15:57
User entered '71.5' in	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:04:39

US3912163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:19:18

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Timothy Vachris (b) (4) (b) (4)	05 Oct 2020 13:03:13
User entered '246.0' lb	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:04:39

US3912163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User accepted default value 'Post-Dose (POSTDOSE)'	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:04:39

US3912163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:04:39

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '15 Sep 2020'	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:04:39

US3912163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '12:17'	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:04:39

US3912163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered '15 Sep 2020 12:17'	System	16 Sep 2020 20:04:39

US3912163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '37.1' C	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:04:39

US3912163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Oral (Oral)'	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:04:39

US3912163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered empty.	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:04:39

US3912163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '63'	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:04:39

US3912163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered 'bpm'	System	16 Sep 2020 20:04:39

US3912163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '14'	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:04:39

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered 'breaths/min'	System	16 Sep 2020 20:04:39

US3912163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User closed query 'Per CDM: Per CCG V2.0 page 50, SBP ≤ 89 or ≥141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 11:56:53
Query 'Per CDM: Per CCG V2.0 page 50, SBP ≤ 89 or ≥141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' answered with 'Investigator deemed NCS' (Site from DM).	Mia Rountree (b) (4) (b) (4)	26 Oct 2020 20:09:07
User opened query 'Per CDM: Per CCG V2.0 page 50, SBP ≤ 89 or ≥141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 13:19:12
User entered '148'	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:04:39

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered 'mmHg'	System	16 Sep 2020 20:04:39

US3912163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '81'	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:04:39

US3912163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered 'mmHg'	System	16 Sep 2020 20:04:39

US3912163
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 10 Jun 2021 10:19:18
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'No (N)'	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:05:03

US3912163
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 10 Jun 2021 10:19:18
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered empty.	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:05:03

US3912163
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 10:19:18

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:44:57

US3912163
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 10:19:18
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered empty.	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:44:57

US3912163

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:19:18

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered empty.	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:44:57

US3912163
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 10:19:18
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered 'MRNA-1273 OR PLACEBO'	System	15 Sep 2020 16:44:57

US3912163

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:19:18

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '15 Sep 2020'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:44:57

Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 10:19:18

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '11:38'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:44:57

US3912163

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:19:18

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered '15 Sep 2020 11:38'	System	15 Sep 2020 16:44:57

US3912163
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 10:19:18
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Left Arm (LEFT ARM)'	Tina Rountree (b) (4) (b) (4)	15 Sep 2020 16:44:57

US3912163
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 10:19:18
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered 'ONCE'	System	15 Sep 2020 16:44:57

Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 10:19:18
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered 'INTRAMUSCULAR'	System	15 Sep 2020 16:44:57

US3912163

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:18

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:05:41

US3912163

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:18

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '15 Sep 2020'	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:05:41

US3912163

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:18

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '11:20'	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:05:41

US3912163

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:18

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered '15 Sep 2020 11:20'	System	16 Sep 2020 20:05:41

US3912163

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:19:18

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	16 Sep 2020 20:06:03
Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System).	System	16 Sep 2020 20:06:03
User entered '15 Sep 2020' reason for change: Data Entry Error	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:06:03
User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	16 Sep 2020 20:05:56
User entered empty.	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:05:56

US3912163

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:19:18

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:05:56

US3912163

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:19:18

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:05:56

US3912163

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:19:18

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '11:27'	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:05:56

US3912163

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:19:18

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered '15 Sep 2020 11:27'	System	16 Sep 2020 20:06:03
User entered empty.	System	16 Sep 2020 20:05:56

US3912163

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:19:18

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:05:56

US3912163

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:19:18

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'No (N)'	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:05:56

US3912163

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:19:18

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered empty.	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:05:56

US3912163

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:19:18

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered empty.	System	16 Sep 2020 20:05:56

US3912163
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 10:19:18

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Amy Collins (b) (4) (b) (4)	16 Sep 2020 20:06:22

US3912163
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 10:19:18
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered '1'	System	16 Sep 2020 20:06:22

US3912163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	15 Sep 2020 16:44:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 16:44:57

US3912163

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-15T12:19:28', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'bfbc3e08-ace5-44f9-8f34-23e4e20f5dcd'	System	15 Sep 2020 17:19:56
User entered 'Yes (Y)'	System	15 Sep 2020 17:19:56

US3912163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:19:18

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-15T12:19:38', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'bfbc3e08-ace5-44f9-8f34-23e4e20f5dcd'	System	15 Sep 2020 17:19:56
User entered '98.8'	System	15 Sep 2020 17:19:56

US3912163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:19:18

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-15T12:19:44', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'bfbc3e08-ace5-44f9-8f34-23e4e20f5dcd'	System	15 Sep 2020 17:19:56
User entered 'No (N)'	System	15 Sep 2020 17:19:56

US3912163

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:18

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-15T12:19:54', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'bfbc3e08-ace5-44f9-8f34-23e4e20f5dcd'	System	15 Sep 2020 17:19:56
User entered '15 Sep 2020 12:19'	System	15 Sep 2020 17:19:56

US3912163

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:18

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '15 Sep 2020 11:58'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:19:18
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '15 Sep 2020 14:28'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	15 Sep 2020 16:44:57
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 16:44:57

US3912163

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-15T15:25:30', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '71765e7a-87c3-4f1c-821e-2ec9e0c9bc37'	System	15 Sep 2020 20:25:56
User entered 'Yes (Y)'	System	15 Sep 2020 20:25:56

US3912163

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:18

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-15T15:25:42', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '71765e7a-87c3-4f1c-821e-2ec9e0c9bc37'	System	15 Sep 2020 20:25:56
User entered '97.8'	System	15 Sep 2020 20:25:56

US3912163

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:18

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-15T15:25:47', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '71765e7a-87c3-4f1c-821e-2ec9e0c9bc37'	System	15 Sep 2020 20:25:56
User entered 'No (N)'	System	15 Sep 2020 20:25:56

FDA-CBER-2022-1614-3508820

US3912163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:19:18
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-15T15:25:52', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '71765e7a-87c3-4f1c-821e-2ec9e0c9bc37'	System	15 Sep 2020 20:25:56
User entered '15 Sep 2020 15:25'	System	15 Sep 2020 20:25:56

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '15 Sep 2020 15:23'	System	15 Sep 2020 16:44:57

FDA-CBER-2022-1614-3508822

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	15 Sep 2020 16:44:57
User entered 'Day 2'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:19:18
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-16T12:00:57', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'f369404b-45f6-4c8a-87eb-173df6c1428b'	System	16 Sep 2020 17:02:05
User entered 'Yes (Y)'	System	16 Sep 2020 17:02:05

US3912163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:19:18

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-16T12:01:07', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'f369404b-45f6-4c8a-87eb-173df6c1428b'	System	16 Sep 2020 17:02:05
User entered '99.0'	System	16 Sep 2020 17:02:05

US3912163

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:18

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-16T12:01:12', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'f369404b-45f6-4c8a-87eb-173df6c1428b'	System	16 Sep 2020 17:02:05
User entered 'No (N)'	System	16 Sep 2020 17:02:05

US3912163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:19:18
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-16T12:01:19', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'f369404b-45f6-4c8a-87eb-173df6c1428b'	System	16 Sep 2020 17:02:05
User entered '16 Sep 2020 12:01'	System	16 Sep 2020 17:02:05

US3912163

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:18

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 16:44:57

US3912163

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:18

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	15 Sep 2020 16:44:57
User entered 'Day 3'	System	15 Sep 2020 16:44:57

US3912163

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-17T12:32:07', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '719d4de7-dea1-4519-b2b2-be86f8b37bff'	System	17 Sep 2020 17:32:27
User entered 'Yes (Y)'	System	17 Sep 2020 17:32:27

US3912163

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:18

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-17T12:32:18', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '719d4de7-dea1-4519-b2b2-be86f8b37bff'	System	17 Sep 2020 17:32:27
User entered '98.4'	System	17 Sep 2020 17:32:27

US3912163

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:18

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-17T12:32:22', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '719d4de7-dea1-4519-b2b2-be86f8b37bff'	System	17 Sep 2020 17:32:27
User entered 'No (N)'	System	17 Sep 2020 17:32:27

US3912163

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:18

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-17T12:32:26', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '719d4de7-dea1-4519-b2b2-be86f8b37bff'	System	17 Sep 2020 17:32:27
User entered '17 Sep 2020 12:32'	System	17 Sep 2020 17:32:27

US3912163

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:18

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 16:44:57

US3912163

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:18

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	15 Sep 2020 16:44:57
User entered 'Day 4'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:19:18
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-18T12:20:01', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'e03141ab-797f-435f-a7e8-62d13aa02c72'	System	18 Sep 2020 17:20:19
User entered 'Yes (Y)'	System	18 Sep 2020 17:20:19

US3912163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:19:18

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-18T12:20:11', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'e03141ab-797f-435f-a7e8-62d13aa02c72'	System	18 Sep 2020 17:20:19
User entered '98.4'	System	18 Sep 2020 17:20:19

US3912163

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:18

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-18T12:20:14', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'e03141ab-797f-435f-a7e8-62d13aa02c72'	System	18 Sep 2020 17:20:19
User entered 'No (N)'	System	18 Sep 2020 17:20:19

US3912163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:19:18
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-18T12:20:18', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'e03141ab-797f-435f-a7e8-62d13aa02c72'	System	18 Sep 2020 17:20:19
User entered '18 Sep 2020 12:20'	System	18 Sep 2020 17:20:19

US3912163

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:18

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 16:44:57

US3912163

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:18

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	15 Sep 2020 16:44:57
User entered 'Day 5'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:19:18
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-19T12:05:53', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '3d6ea300-7302-4e5e-9051-a0d910338b43'	System	19 Sep 2020 17:06:11
User entered 'Yes (Y)'	System	19 Sep 2020 17:06:11

US3912163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:19:18

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-19T12:05:59', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '3d6ea300-7302-4e5e-9051-a0d910338b43'	System	19 Sep 2020 17:06:11
User entered '98.7'	System	19 Sep 2020 17:06:11

US3912163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:19:18
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-19T12:06:03', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '3d6ea300-7302-4e5e-9051-a0d910338b43'	System	19 Sep 2020 17:06:11
User entered 'No (N)'	System	19 Sep 2020 17:06:11

US3912163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:19:18
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-19T12:06:09', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '3d6ea300-7302-4e5e-9051-a0d910338b43'	System	19 Sep 2020 17:06:11
User entered '19 Sep 2020 12:06'	System	19 Sep 2020 17:06:11

US3912163

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:18

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:19:18
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	15 Sep 2020 16:44:57
User entered 'Day 6'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:19:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-20T12:01:21', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'b07275e1-8874-461c-9584-40a9f3a771d1'	System	20 Sep 2020 17:01:54
User entered 'Yes (Y)'	System	20 Sep 2020 17:01:54

US3912163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:19:18

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-20T12:01:30', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'b07275e1-8874-461c-9584-40a9f3a771d1'	System	20 Sep 2020 17:01:54
User entered '98.6'	System	20 Sep 2020 17:01:54

US3912163

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:18

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-20T12:01:33', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'b07275e1-8874-461c-9584-40a9f3a771d1'	System	20 Sep 2020 17:01:54
User entered 'No (N)'	System	20 Sep 2020 17:01:54

US3912163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:19:18
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-20T12:01:36', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'b07275e1-8874-461c-9584-40a9f3a771d1'	System	20 Sep 2020 17:01:54
User entered '20 Sep 2020 12:01'	System	20 Sep 2020 17:01:54

US3912163

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:18

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 16:44:57

US3912163

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:18

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	15 Sep 2020 16:44:57
User entered 'Day 7'	System	15 Sep 2020 16:44:57

US3912163

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-21T12:00:41', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '2cedecd4-cca8-47bf-8843-650a9f905e26'	System	21 Sep 2020 17:03:43
User entered 'Yes (Y)'	System	21 Sep 2020 17:03:43

US3912163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:19:18

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-21T12:00:48', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '2cedecd4-cca8-47bf-8843-650a9f905e26'	System	21 Sep 2020 17:03:43
User entered '97.8'	System	21 Sep 2020 17:03:43

US3912163

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:18

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-21T12:00:51', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '2cedecd4-cca8-47bf-8843-650a9f905e26'	System	21 Sep 2020 17:03:43
User entered 'No (N)'	System	21 Sep 2020 17:03:43

FDA-CBER-2022-1614-3508862

US3912163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:19:18
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-21T12:00:53', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '2cedecd4-cca8-47bf-8843-650a9f905e26'	System	21 Sep 2020 17:03:43
User entered '21 Sep 2020 12:00'	System	21 Sep 2020 17:03:43

US3912163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:19:18
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 16:44:57

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	15 Sep 2020 16:44:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 16:44:57

US3912163

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:18

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-15T12:20:25', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'df661a83-6f67-4b74-979a-dc3ab7becda6'	System	15 Sep 2020 17:21:01
User entered 'None (1)'	System	15 Sep 2020 17:21:01

US3912163

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:18

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-15T12:20:29', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'df661a83-6f67-4b74-979a-dc3ab7becda6'	System	15 Sep 2020 17:21:01
User entered 'No (N)'	System	15 Sep 2020 17:21:01

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US3912163

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-15T12:20:33', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'df661a83-6f67-4b74-979a-dc3ab7becda6'	System	15 Sep 2020 17:21:01
User entered 'No (N)'	System	15 Sep 2020 17:21:01

US3912163

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:18

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-15T12:20:55', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'df661a83-6f67-4b74-979a-dc3ab7becda6'	System	15 Sep 2020 17:21:01
User entered 'None (1)'	System	15 Sep 2020 17:21:01

US3912163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:19:18
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-15T12:20:59', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'df661a83-6f67-4b74-979a-dc3ab7becda6'	System	15 Sep 2020 17:21:01
User entered '15 Sep 2020 12:20'	System	15 Sep 2020 17:21:01

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '15 Sep 2020 11:58'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:19:18
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '15 Sep 2020 14:28'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	15 Sep 2020 16:44:57
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:19:18

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-15T15:25:58', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '5c3ed21d-2bdf-4411-ba67-60ae2db127e5'	System	15 Sep 2020 20:26:16
User entered 'None (1)'	System	15 Sep 2020 20:26:16

US3912163

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:18

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-15T15:26:02', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '5c3ed21d-2bdf-4411-ba67-60ae2db127e5'	System	15 Sep 2020 20:26:16
User entered 'No (N)'	System	15 Sep 2020 20:26:16

US3912163

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-15T15:26:06', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '5c3ed21d-2bdf-4411-ba67-60ae2db127e5'	System	15 Sep 2020 20:26:16
User entered 'No (N)'	System	15 Sep 2020 20:26:16

US3912163

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:18

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-15T15:26:12', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '5c3ed21d-2bdf-4411-ba67-60ae2db127e5'	System	15 Sep 2020 20:26:16
User entered 'None (1)'	System	15 Sep 2020 20:26:16

US3912163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:19:18
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-15T15:26:15', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '5c3ed21d-2bdf-4411-ba67-60ae2db127e5'	System	15 Sep 2020 20:26:16
User entered '15 Sep 2020 15:26'	System	15 Sep 2020 20:26:16

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '15 Sep 2020 15:23'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:19:18
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	15 Sep 2020 16:44:57
User entered 'Day 2'	System	15 Sep 2020 16:44:57

US3912163

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:18

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-16T12:01:26', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'ff39c6be-1e75-47fb-b48e-fc87fc686231'	System	16 Sep 2020 17:02:47
User entered 'None (1)'	System	16 Sep 2020 17:02:47

US3912163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:19:18

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-16T12:01:30', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'ff39c6be-1e75-47fb-b48e-fc87fc686231'	System	16 Sep 2020 17:02:47
User entered 'No (N)'	System	16 Sep 2020 17:02:47

US3912163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:19:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-16T12:01:33', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'ff39c6be-1e75-47fb-b48e-fc87fc686231'	System	16 Sep 2020 17:02:47
User entered 'No (N)'	System	16 Sep 2020 17:02:47

US3912163

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:18

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-16T12:01:43', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'ff39c6be-1e75-47fb-b48e-fc87fc686231'	System	16 Sep 2020 17:02:47
User entered 'None (1)'	System	16 Sep 2020 17:02:47

US3912163

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:18

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-16T12:01:48', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'ff39c6be-1e75-47fb-b48e-fc87fc686231'	System	16 Sep 2020 17:02:47
User entered '16 Sep 2020 12:01'	System	16 Sep 2020 17:02:47

US3912163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:19:18
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:19:18
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	15 Sep 2020 16:44:57
User entered 'Day 3'	System	15 Sep 2020 16:44:57

US3912163

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:18

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-17T12:32:33', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '64f8d29e-ce73-4473-9cfb-edf5e6de5053'	System	17 Sep 2020 17:32:54
User entered 'None (1)'	System	17 Sep 2020 17:32:54

US3912163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:19:18
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-17T12:32:36', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '64f8d29e-ce73-4473-9cfb-edf5e6de5053'	System	17 Sep 2020 17:32:54
User entered 'No (N)'	System	17 Sep 2020 17:32:54

US3912163

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-17T12:32:40', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '64f8d29e-ce73-4473-9cfb-edf5e6de5053'	System	17 Sep 2020 17:32:54
User entered 'No (N)'	System	17 Sep 2020 17:32:54

US3912163

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:18

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-17T12:32:43', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '64f8d29e-ce73-4473-9cfb-edf5e6de5053'	System	17 Sep 2020 17:32:54
User entered 'None (1)'	System	17 Sep 2020 17:32:54

US3912163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:19:18
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-17T12:32:52', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '64f8d29e-ce73-4473-9cfb-edf5e6de5053'	System	17 Sep 2020 17:32:54
User entered '17 Sep 2020 12:32'	System	17 Sep 2020 17:32:54

US3912163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:19:18
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 16:44:57

US3912163

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:18

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	15 Sep 2020 16:44:57
User entered 'Day 4'	System	15 Sep 2020 16:44:57

US3912163

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:18

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-18T12:20:22', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '7ec9d30e-223d-4e8e-9e14-17a65d5a0d2d'	System	18 Sep 2020 17:20:37
User entered 'None (1)'	System	18 Sep 2020 17:20:37

US3912163

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:18

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-18T12:20:25', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '7ec9d30e-223d-4e8e-9e14-17a65d5a0d2d'	System	18 Sep 2020 17:20:37
User entered 'No (N)'	System	18 Sep 2020 17:20:37

US3912163

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-18T12:20:28', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '7ec9d30e-223d-4e8e-9e14-17a65d5a0d2d'	System	18 Sep 2020 17:20:37
User entered 'No (N)'	System	18 Sep 2020 17:20:37

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US3912163

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:18

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-18T12:20:31', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '7ec9d30e-223d-4e8e-9e14-17a65d5a0d2d'	System	18 Sep 2020 17:20:37
User entered 'None (1)'	System	18 Sep 2020 17:20:37

US3912163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:19:18
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-18T12:20:34', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '7ec9d30e-223d-4e8e-9e14-17a65d5a0d2d'	System	18 Sep 2020 17:20:37
User entered '18 Sep 2020 12:20'	System	18 Sep 2020 17:20:37

US3912163

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:18

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:19:18
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	15 Sep 2020 16:44:57
User entered 'Day 5'	System	15 Sep 2020 16:44:57

US3912163

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:18

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-19T12:06:12', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '05ca4a7b-4355-4950-9557-75e6499163b2'	System	19 Sep 2020 17:06:25
User entered 'None (1)'	System	19 Sep 2020 17:06:25

US3912163

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:18

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-19T12:06:15', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '05ca4a7b-4355-4950-9557-75e6499163b2'	System	19 Sep 2020 17:06:25
User entered 'No (N)'	System	19 Sep 2020 17:06:25

US3912163

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-19T12:06:18', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '05ca4a7b-4355-4950-9557-75e6499163b2'	System	19 Sep 2020 17:06:25
User entered 'No (N)'	System	19 Sep 2020 17:06:25

US3912163

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:18

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-19T12:06:20', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '05ca4a7b-4355-4950-9557-75e6499163b2'	System	19 Sep 2020 17:06:25
User entered 'None (1)'	System	19 Sep 2020 17:06:25

US3912163

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:18

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-19T12:06:23', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '05ca4a7b-4355-4950-9557-75e6499163b2'	System	19 Sep 2020 17:06:25
User entered '19 Sep 2020 12:06'	System	19 Sep 2020 17:06:25

US3912163

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:18

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 16:44:57

US3912163

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:18

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	15 Sep 2020 16:44:57
User entered 'Day 6'	System	15 Sep 2020 16:44:57

US3912163

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:18

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-20T12:01:40', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'd6ec4b11-3c10-4e88-92d6-496eb61e5357'	System	20 Sep 2020 17:02:10
User entered 'None (1)'	System	20 Sep 2020 17:02:10

US3912163

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:18

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-20T12:01:43', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'd6ec4b11-3c10-4e88-92d6-496eb61e5357'	System	20 Sep 2020 17:02:10
User entered 'No (N)'	System	20 Sep 2020 17:02:10

US3912163

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-20T12:01:45', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'd6ec4b11-3c10-4e88-92d6-496eb61e5357'	System	20 Sep 2020 17:02:10
User entered 'No (N)'	System	20 Sep 2020 17:02:10

US3912163

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:18

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-20T12:01:47', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'd6ec4b11-3c10-4e88-92d6-496eb61e5357'	System	20 Sep 2020 17:02:10
User entered 'None (1)'	System	20 Sep 2020 17:02:10

US3912163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:19:18
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-20T12:01:50', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'd6ec4b11-3c10-4e88-92d6-496eb61e5357'	System	20 Sep 2020 17:02:10
User entered '20 Sep 2020 12:01'	System	20 Sep 2020 17:02:10

US3912163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:19:18
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 16:44:57

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	15 Sep 2020 16:44:57
User entered 'Day 7'	System	15 Sep 2020 16:44:57

US3912163

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:18

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-21T12:00:57', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '373c989b-3345-4241-bcc1-3d87d1f68a69'	System	21 Sep 2020 17:04:07
User entered 'None (1)'	System	21 Sep 2020 17:04:07

US3912163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:19:18
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-21T12:01:01', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '373c989b-3345-4241-bcc1-3d87d1f68a69'	System	21 Sep 2020 17:04:07
User entered 'No (N)'	System	21 Sep 2020 17:04:07

US3912163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:19:18
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-21T12:01:02', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '373c989b-3345-4241-bcc1-3d87d1f68a69'	System	21 Sep 2020 17:04:07
User entered 'No (N)'	System	21 Sep 2020 17:04:07

US3912163

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:18

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-21T12:01:04', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '373c989b-3345-4241-bcc1-3d87d1f68a69'	System	21 Sep 2020 17:04:07
User entered 'None (1)'	System	21 Sep 2020 17:04:07

US3912163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:19:18
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-21T12:01:06', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '373c989b-3345-4241-bcc1-3d87d1f68a69'	System	21 Sep 2020 17:04:07
User entered '21 Sep 2020 12:01'	System	21 Sep 2020 17:04:07

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:19:18
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	15 Sep 2020 16:44:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:19:18
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-15T12:21:08', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '3f7aa8c7-c1f7-40fb-9366-d72141f6fb21'	System	15 Sep 2020 17:21:38
User entered 'None (0)'	System	15 Sep 2020 17:21:38

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:19:18
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-15T12:21:12', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '3f7aa8c7-c1f7-40fb-9366-d72141f6fb21'	System	15 Sep 2020 17:21:38
User entered 'None (0)'	System	15 Sep 2020 17:21:38

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:19:18
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-15T12:21:16', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '3f7aa8c7-c1f7-40fb-9366-d72141f6fb21'	System	15 Sep 2020 17:21:38
User entered 'None (0)'	System	15 Sep 2020 17:21:38

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:19:18
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-15T12:21:20', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '3f7aa8c7-c1f7-40fb-9366-d72141f6fb21'	System	15 Sep 2020 17:21:38
User entered 'None (0)'	System	15 Sep 2020 17:21:38

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:19:18
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-15T12:21:23', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '3f7aa8c7-c1f7-40fb-9366-d72141f6fb21'	System	15 Sep 2020 17:21:38
User entered 'None (0)'	System	15 Sep 2020 17:21:38

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:19:18
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-15T12:21:25', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '3f7aa8c7-c1f7-40fb-9366-d72141f6fb21'	System	15 Sep 2020 17:21:38
User entered 'None (0)'	System	15 Sep 2020 17:21:38

US3912163

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:18

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-15T12:21:30', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '3f7aa8c7-c1f7-40fb-9366-d72141f6fb21'	System	15 Sep 2020 17:21:38
User entered 'No (N)'	System	15 Sep 2020 17:21:38

US3912163

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:18

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-15T12:21:35', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '3f7aa8c7-c1f7-40fb-9366-d72141f6fb21'	System	15 Sep 2020 17:21:38
User entered '15 Sep 2020 12:21'	System	15 Sep 2020 17:21:38

US3912163

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:18

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '15 Sep 2020 11:58'	System	15 Sep 2020 16:44:57

US3912163

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:18

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '15 Sep 2020 14:28'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	15 Sep 2020 16:44:57
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:19:18
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-15T15:26:26', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'f443a14f-99fa-4601-b46d-acb9d619ba35'	System	15 Sep 2020 20:27:12
User entered 'None (0)'	System	15 Sep 2020 20:27:12

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:19:18
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-15T15:26:38', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'f443a14f-99fa-4601-b46d-acb9d619ba35'	System	15 Sep 2020 20:27:12
User entered 'No interference with activity (1)'	System	15 Sep 2020 20:27:12

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:19:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-15T15:26:48', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'f443a14f-99fa-4601-b46d-acb9d619ba35'	System	15 Sep 2020 20:27:12
User entered 'None (0)'	System	15 Sep 2020 20:27:12

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:19:18
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-15T15:26:52', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'f443a14f-99fa-4601-b46d-acb9d619ba35'	System	15 Sep 2020 20:27:12
User entered 'None (0)'	System	15 Sep 2020 20:27:12

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:19:18
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-15T15:26:56', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'f443a14f-99fa-4601-b46d-acb9d619ba35'	System	15 Sep 2020 20:27:12
User entered 'None (0)'	System	15 Sep 2020 20:27:12

US3912163

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-15T15:27:00', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'f443a14f-99fa-4601-b46d-acb9d619ba35'	System	15 Sep 2020 20:27:12
User entered 'None (0)'	System	15 Sep 2020 20:27:12

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:19:18

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-15T15:27:05', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'f443a14f-99fa-4601-b46d-acb9d619ba35'	System	15 Sep 2020 20:27:12
User entered 'No (N)'	System	15 Sep 2020 20:27:12

US3912163

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:18

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-15T15:27:09', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'f443a14f-99fa-4601-b46d-acb9d619ba35'	System	15 Sep 2020 20:27:12
User entered '15 Sep 2020 15:27'	System	15 Sep 2020 20:27:12

US3912163

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:18

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '15 Sep 2020 15:23'	System	15 Sep 2020 16:44:57

US3912163

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:18

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	15 Sep 2020 16:44:57
User entered 'Day 2'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:19:18
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-16T12:02:00', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'acfe82b6-2ca4-4569-b684-246323001a00'	System	16 Sep 2020 17:03:41
User entered 'No interference with activity (1)'	System	16 Sep 2020 17:03:41

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:19:18
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-16T12:02:06', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'acfe82b6-2ca4-4569-b684-246323001a00'	System	16 Sep 2020 17:03:41
User entered 'No interference with activity (1)'	System	16 Sep 2020 17:03:41

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:19:18
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-16T12:02:11', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'acfe82b6-2ca4-4569-b684-246323001a00'	System	16 Sep 2020 17:03:41
User entered 'None (0)'	System	16 Sep 2020 17:03:41

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:19:18
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-16T12:02:16', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'acfe82b6-2ca4-4569-b684-246323001a00'	System	16 Sep 2020 17:03:41
User entered 'None (0)'	System	16 Sep 2020 17:03:41

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:19:18
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-16T12:02:21', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'acfe82b6-2ca4-4569-b684-246323001a00'	System	16 Sep 2020 17:03:41
User entered 'None (0)'	System	16 Sep 2020 17:03:41

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:19:18
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-16T12:02:27', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'acfe82b6-2ca4-4569-b684-246323001a00'	System	16 Sep 2020 17:03:41
User entered 'No interference with activity (1)'	System	16 Sep 2020 17:03:41

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:19:18
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-16T12:02:34', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'acfe82b6-2ca4-4569-b684-246323001a00'	System	16 Sep 2020 17:03:41
User entered 'No (N)'	System	16 Sep 2020 17:03:41

US3912163

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:18

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-16T12:02:50', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'acfe82b6-2ca4-4569-b684-246323001a00'	System	16 Sep 2020 17:03:41
User entered '16 Sep 2020 12:02'	System	16 Sep 2020 17:03:41

US3912163

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:18

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 16:44:57

US3912163

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:18

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	15 Sep 2020 16:44:57
User entered 'Day 3'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:19:18
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-17T12:33:01', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '410f38dd-49e9-4fa4-9610-66873633ca68'	System	17 Sep 2020 17:33:36
User entered 'None (0)'	System	17 Sep 2020 17:33:36

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:19:18
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-17T12:33:06', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '410f38dd-49e9-4fa4-9610-66873633ca68'	System	17 Sep 2020 17:33:36
User entered 'No interference with activity (1)'	System	17 Sep 2020 17:33:36

US3912163

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-17T12:33:09', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '410f38dd-49e9-4fa4-9610-66873633ca68'	System	17 Sep 2020 17:33:36
User entered 'None (0)'	System	17 Sep 2020 17:33:36

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:19:18
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-17T12:33:13', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '410f38dd-49e9-4fa4-9610-66873633ca68'	System	17 Sep 2020 17:33:36
User entered 'None (0)'	System	17 Sep 2020 17:33:36

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:19:18
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-17T12:33:16', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '410f38dd-49e9-4fa4-9610-66873633ca68'	System	17 Sep 2020 17:33:36
User entered 'None (0)'	System	17 Sep 2020 17:33:36

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:19:18
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-17T12:33:21', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '410f38dd-49e9-4fa4-9610-66873633ca68'	System	17 Sep 2020 17:33:36
User entered 'None (0)'	System	17 Sep 2020 17:33:36

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:19:18

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-17T12:33:25', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '410f38dd-49e9-4fa4-9610-66873633ca68'	System	17 Sep 2020 17:33:36
User entered 'No (N)'	System	17 Sep 2020 17:33:36

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:19:18
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-17T12:33:32', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '410f38dd-49e9-4fa4-9610-66873633ca68'	System	17 Sep 2020 17:33:36
User entered '17 Sep 2020 12:33'	System	17 Sep 2020 17:33:36

US3912163

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:18

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 16:44:57

US3912163

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:18

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	15 Sep 2020 16:44:57
User entered 'Day 4'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:19:18
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-18T12:20:38', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'e46a1d8b-47ad-447a-bccd-dea4c592b52e'	System	18 Sep 2020 17:21:00
User entered 'None (0)'	System	18 Sep 2020 17:21:00

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:19:18
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-18T12:20:40', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'e46a1d8b-47ad-447a-bccd-dea4c592b52e'	System	18 Sep 2020 17:21:00
User entered 'None (0)'	System	18 Sep 2020 17:21:00

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:19:18
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-18T12:20:42', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'e46a1d8b-47ad-447a-bccd-dea4c592b52e'	System	18 Sep 2020 17:21:00
User entered 'None (0)'	System	18 Sep 2020 17:21:00

FDA-CBER-2022-1614-3508977

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:19:18
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-18T12:20:44', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'e46a1d8b-47ad-447a-bccd-dea4c592b52e'	System	18 Sep 2020 17:21:00
User entered 'None (0)'	System	18 Sep 2020 17:21:00

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:19:18
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-18T12:20:47', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'e46a1d8b-47ad-447a-bccd-dea4c592b52e'	System	18 Sep 2020 17:21:00
User entered 'None (0)'	System	18 Sep 2020 17:21:00

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:19:18
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-18T12:20:49', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'e46a1d8b-47ad-447a-bccd-dea4c592b52e'	System	18 Sep 2020 17:21:00
User entered 'None (0)'	System	18 Sep 2020 17:21:00

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:19:18

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-18T12:20:53', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'e46a1d8b-47ad-447a-bccd-dea4c592b52e'	System	18 Sep 2020 17:21:00
User entered 'No (N)'	System	18 Sep 2020 17:21:00

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:19:18
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-18T12:20:57', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'e46a1d8b-47ad-447a-bccd-dea4c592b52e'	System	18 Sep 2020 17:21:00
User entered '18 Sep 2020 12:20'	System	18 Sep 2020 17:21:00

US3912163

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:18

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 16:44:57

US3912163

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:18

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	15 Sep 2020 16:44:57
User entered 'Day 5'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:19:18
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-19T12:06:26', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'bd807622-97dd-4d11-9222-7a8d8b641750'	System	19 Sep 2020 17:06:47
User entered 'None (0)'	System	19 Sep 2020 17:06:47

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:19:18
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-19T12:06:30', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'bd807622-97dd-4d11-9222-7a8d8b641750'	System	19 Sep 2020 17:06:47
User entered 'None (0)'	System	19 Sep 2020 17:06:47

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:19:18
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-19T12:06:32', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'bd807622-97dd-4d11-9222-7a8d8b641750'	System	19 Sep 2020 17:06:47
User entered 'None (0)'	System	19 Sep 2020 17:06:47

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:19:18
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-19T12:06:33', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'bd807622-97dd-4d11-9222-7a8d8b641750'	System	19 Sep 2020 17:06:47
User entered 'None (0)'	System	19 Sep 2020 17:06:47

US3912163

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-19T12:06:35', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'bd807622-97dd-4d11-9222-7a8d8b641750'	System	19 Sep 2020 17:06:47
User entered 'None (0)'	System	19 Sep 2020 17:06:47

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:19:18
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-19T12:06:37', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'bd807622-97dd-4d11-9222-7a8d8b641750'	System	19 Sep 2020 17:06:47
User entered 'None (0)'	System	19 Sep 2020 17:06:47

US3912163

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:18

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-19T12:06:41', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'bd807622-97dd-4d11-9222-7a8d8b641750'	System	19 Sep 2020 17:06:47
User entered 'No (N)'	System	19 Sep 2020 17:06:47

US3912163

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:18

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-19T12:06:44', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'bd807622-97dd-4d11-9222-7a8d8b641750'	System	19 Sep 2020 17:06:47
User entered '19 Sep 2020 12:06'	System	19 Sep 2020 17:06:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 16:44:57

US3912163

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:18

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	15 Sep 2020 16:44:57
User entered 'Day 6'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:19:18
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-20T12:01:56', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '9b66ee01-287b-4479-b5b8-e4f0bcd94efc'	System	20 Sep 2020 17:03:07
User entered 'No interference with activity (1)'	System	20 Sep 2020 17:03:07

US3912163

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-20T12:02:02', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '9b66ee01-287b-4479-b5b8-e4f0bcd94efc'	System	20 Sep 2020 17:03:07
User entered 'None (0)'	System	20 Sep 2020 17:03:07

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:19:18
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-20T12:02:05', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '9b66ee01-287b-4479-b5b8-e4f0bcd94efc'	System	20 Sep 2020 17:03:07
User entered 'None (0)'	System	20 Sep 2020 17:03:07

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:19:18
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-20T12:02:07', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '9b66ee01-287b-4479-b5b8-e4f0bcd94efc'	System	20 Sep 2020 17:03:07
User entered 'None (0)'	System	20 Sep 2020 17:03:07

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:19:18
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-20T12:02:09', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '9b66ee01-287b-4479-b5b8-e4f0bcd94efc'	System	20 Sep 2020 17:03:07
User entered 'None (0)'	System	20 Sep 2020 17:03:07

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:19:18
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-20T12:02:11', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '9b66ee01-287b-4479-b5b8-e4f0bcd94efc'	System	20 Sep 2020 17:03:07
User entered 'None (0)'	System	20 Sep 2020 17:03:07

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:19:18
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-20T12:02:14', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '9b66ee01-287b-4479-b5b8-e4f0bcd94efc'	System	20 Sep 2020 17:03:07
User entered 'No (N)'	System	20 Sep 2020 17:03:07

US3912163

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:18

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-20T12:02:17', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '9b66ee01-287b-4479-b5b8-e4f0bcd94efc'	System	20 Sep 2020 17:03:07
User entered '20 Sep 2020 12:02'	System	20 Sep 2020 17:03:07

US3912163

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:18

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 16:44:57

US3912163

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:18

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	15 Sep 2020 16:44:57
User entered 'Day 7'	System	15 Sep 2020 16:44:57

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:19:18
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-21T12:01:10', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'd174a1b2-6f56-4b52-8f61-2298996aa9f9'	System	21 Sep 2020 17:04:27
User entered 'None (0)'	System	21 Sep 2020 17:04:27

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:19:18
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-21T12:01:11', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'd174a1b2-6f56-4b52-8f61-2298996aa9f9'	System	21 Sep 2020 17:04:27
User entered 'None (0)'	System	21 Sep 2020 17:04:27

US3912163

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-21T12:01:12', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'd174a1b2-6f56-4b52-8f61-2298996aa9f9'	System	21 Sep 2020 17:04:27
User entered 'None (0)'	System	21 Sep 2020 17:04:27

FDA-CBER-2022-1614-3509010

US3912163

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-21T12:01:14', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'd174a1b2-6f56-4b52-8f61-2298996aa9f9'	System	21 Sep 2020 17:04:27
User entered 'None (0)'	System	21 Sep 2020 17:04:27

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:19:18
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-21T12:01:15', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'd174a1b2-6f56-4b52-8f61-2298996aa9f9'	System	21 Sep 2020 17:04:27
User entered 'None (0)'	System	21 Sep 2020 17:04:27

US3912163
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:19:18
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-21T12:01:17', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'd174a1b2-6f56-4b52-8f61-2298996aa9f9'	System	21 Sep 2020 17:04:27
User entered 'None (0)'	System	21 Sep 2020 17:04:27

US3912163

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:18

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-21T12:01:19', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'd174a1b2-6f56-4b52-8f61-2298996aa9f9'	System	21 Sep 2020 17:04:27
User entered 'No (N)'	System	21 Sep 2020 17:04:27

US3912163

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:18

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-09-21T12:01:21', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'd174a1b2-6f56-4b52-8f61-2298996aa9f9'	System	21 Sep 2020 17:04:27
User entered '21 Sep 2020 12:01'	System	21 Sep 2020 17:04:27

US3912163

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:18

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 16:44:57

US3912163

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:18

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 16:44:57

US3912163

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:18

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 13:49:07

US3912163

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:18

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 13:49:07

US3912163
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:19:18
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 13:49:07

US3912163
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:19:18
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 13:49:07

US3912163

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:18

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 13:49:12

FDA-CBER-2022-1614-3509022

US3912163
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:19:18
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered '1'	System	22 Sep 2020 13:49:12

US3912163

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:18

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
	(b) (4)	
User entered 'Yes (Y)'	Amy Collins (b) (4)	30 Sep 2020 22:05:02
	(b) (4)	

US3912163
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:19:18

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '30 Sep 2020'	Amy Collins (b) (4) (b) (4)	30 Sep 2020 22:05:02

US3912163

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:18

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Contact Made (CONTACT MADE)'	Amy Collins (b) (4) (b) (4)	30 Sep 2020 22:05:02

US3912163

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:18

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered empty.	Amy Collins (b) (4) (b) (4)	30 Sep 2020 22:05:02

US3912163
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:19:18

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Amy Collins (b) (4) (b) (4)	30 Sep 2020 22:05:09

US3912163

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:18

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered '1'	System	30 Sep 2020 22:05:09

US3912163
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:19:18

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'No (N)'	Monique Gawlik (b) (4)	13 Oct 2020 16:53:44

Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:19:18

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
User entered empty.	(b) (4) Monique Gawlik (b) (4)	13 Oct 2020 16:53:44

US3912163
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:19:18
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
User entered empty.	Monique Gawlik (b) (4)	13 Oct 2020 16:53:44

US3912163
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:19:18
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
User closed query 'Per eCRF guidelines v2.0, Page 33: If contact was not made Please provide reason in comment section.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 14:12:44
Query 'Per eCRF guidelines v2.0, Page 33: If contact was not made Please provide reason in comment section.' answered with 'Updated information' (Site from CRA).	Tina Rountree (b) (4) (b) (4)	07 Nov 2020 03:34:06
User entered 'Safety call not attempted due to site error.' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	07 Nov 2020 03:33:58
User opened query 'Per eCRF guidelines v2.0, Page 33: If contact was not made Please provide reason in comment section.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 16:05:35
User entered empty.	Monique Gawlik (b) (4)	13 Oct 2020 16:53:44

Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:19:18

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Monique Gawlik (b) (4)	13 Oct 2020 16:53:51

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered '1'	System	13 Oct 2020 16:53:51

US3912163
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:19:18
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:02:42

US3912163
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:19:18

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '13 Oct 2020'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:02:42

US3912163

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:19:18

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Clinic (Clinic)'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:02:42

US3912163
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:19:18
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered 'VISIT2'	System	19 Oct 2020 15:02:42

US3912163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User accepted default value 'Pre-Dose (PREDOSE)'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 14:58:31

US3912163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 14:58:31

US3912163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '13 Oct 2020'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 14:58:31

US3912163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '09:55'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 14:58:31

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered '13 Oct 2020 09:55'	System	19 Oct 2020 14:58:31

FDA-CBER-2022-1614-3509044

US3912163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '37.0' C	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 14:58:31

US3912163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Oral (Oral)'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 14:58:31

US3912163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:19:18
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered empty.	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 14:58:31

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '66'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 14:58:31

US3912163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:19:18
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered 'bpm'	System	19 Oct 2020 14:58:31

US3912163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:19:18

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '14'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 14:58:31

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered 'breaths/min'	System	19 Oct 2020 14:58:31

FDA-CBER-2022-1614-3509051

US3912163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User closed query 'Per CDM: Per CCG V2.0 page 53, SBP $\leq$ 89 or $\geq$ 141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 08:03:51
Query 'Per CDM: Per CCG V2.0 page 53, SBP $\leq$ 89 or $\geq$ 141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' answered with 'Investigator deemed CS. Vitals repeated 144/92 and then deemed NCS.' (Site from DM).	Mia Rountree (b) (4) (b) (4)	02 Nov 2020 18:12:47
User opened query 'Per CDM: Per CCG V2.0 page 53, SBP $\leq$ 89 or $\geq$ 141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 15:47:27
User entered '157'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 14:58:31

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered 'mmHg'	System	19 Oct 2020 14:58:31

FDA-CBER-2022-1614-3509053

US3912163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 05:29:14
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Investigator deemed CS and AE was created' (Site from System).	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 14:59:29
User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	19 Oct 2020 14:58:31
User entered '119'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 14:58:31

US3912163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:19:18
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered 'mmHg'	System	19 Oct 2020 14:58:31

US3912163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:19:18
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User accepted default value 'Post-Dose (POSTDOSE)'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 14:58:31

US3912163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 14:58:31

US3912163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '13 Oct 2020'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 14:58:31

US3912163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '11:54'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 14:58:31

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered '13 Oct 2020 11:54'	System	19 Oct 2020 14:58:31

FDA-CBER-2022-1614-3509060

US3912163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 05:29:25
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Investigator deemed NCS' (Site from System).	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:06:24
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	19 Oct 2020 14:58:31
User entered '35.9' C	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 14:58:31

US3912163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Oral (Oral)'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 14:58:31

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered empty.	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 14:58:31

US3912163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '57'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 14:58:31

US3912163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:19:18
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered 'bpm'	System	19 Oct 2020 14:58:31

US3912163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:19:18
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '16'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 14:58:31

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered 'breaths/min'	System	19 Oct 2020 14:58:31

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US3912163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '136'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 14:58:31

US3912163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered 'mmHg'	System	19 Oct 2020 14:58:31

US3912163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '88'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 14:58:31

US3912163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered 'mmHg'	System	19 Oct 2020 14:58:31

US3912163

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:19:18

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:03:02

Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 10:19:18

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '13 Oct 2020'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:03:02

US3912163
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 10:19:18

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Monique Gawlik (b) (4)	13 Oct 2020 16:54:17

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US3912163
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 10:19:18
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
User entered empty.	(b) (4) Monique Gawlik (b) (4)	13 Oct 2020 16:54:17

US3912163

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:19:18

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered empty.	Monique Gawlik (b) (4)	13 Oct 2020 16:54:17

What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered 'MRNA-1273 OR PLACEBO'	System	13 Oct 2020 16:54:17

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
User entered '13 Oct 2020'	Monique Gawlik (b) (4)	13 Oct 2020 16:54:17

US3912163

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:19:18

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '11:11'	Monique Gawlik (b) (4)	13 Oct 2020 16:54:17

US3912163
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 10:19:18

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered '13 Oct 2020 11:11'	System	13 Oct 2020 16:54:17

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
User entered 'Left Arm (LEFT ARM)'	Monique Gawlik (b) (4)	13 Oct 2020 16:54:17

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US3912163
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 10:19:18
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered 'ONCE'	System	13 Oct 2020 16:54:17

US3912163

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:19:18

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered 'INTRAMUSCULAR'	System	13 Oct 2020 16:54:17

Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 10:19:18
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:03:28

US3912163

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:18

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '13 Oct 2020'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:03:28

US3912163

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:18

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '10:47'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:03:28

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered '13 Oct 2020 10:47'	System	19 Oct 2020 15:03:28

US3912163

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:19:18

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '13 Oct 2020'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:03:44

US3912163

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:19:18

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:03:44

US3912163

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:19:18

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:03:44

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '10:53'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:03:44

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered '13 Oct 2020 10:53'	System	19 Oct 2020 15:03:44

FDA-CBER-2022-1614-3509092

US3912163

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:19:18

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:03:44

Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 10:19:18
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:03:44

US3912163

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:19:18

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered empty.	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:03:44

US3912163

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:19:18

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered empty.	System	19 Oct 2020 15:03:44

US3912163

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:18

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Monique Gawlik (b) (4)	13 Oct 2020 16:58:57

US3912163
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:19:18
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered '1'	System	13 Oct 2020 16:58:57

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	13 Oct 2020 16:54:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:19:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-13T11:58:12', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'a40e01b2-28ff-477a-88ac-9f9a4669a21b'	System	13 Oct 2020 16:58:35
User entered 'Yes (Y)'	System	13 Oct 2020 16:58:35

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:19:18

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-13T11:58:23', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'a40e01b2-28ff-477a-88ac-9f9a4669a21b'	System	13 Oct 2020 16:58:35
User entered '96.7'	System	13 Oct 2020 16:58:35

US3912163

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:18

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-13T11:58:27', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'a40e01b2-28ff-477a-88ac-9f9a4669a21b'	System	13 Oct 2020 16:58:35
User entered 'No (N)'	System	13 Oct 2020 16:58:35

US3912163

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:18

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-13T11:58:33', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'a40e01b2-28ff-477a-88ac-9f9a4669a21b'	System	13 Oct 2020 16:58:35
User entered '13 Oct 2020 11:58'	System	13 Oct 2020 16:58:35

US3912163

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:19:18

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '13 Oct 2020 11:31'	System	13 Oct 2020 16:54:17

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '13 Oct 2020 14:01'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	13 Oct 2020 16:54:17
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:19:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-13T21:16:11', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '7a40d56f-0afb-4d6c-8ef2-a7719768932b'	System	14 Oct 2020 02:16:29
User entered 'Yes (Y)'	System	14 Oct 2020 02:16:29

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:19:18

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-13T21:16:16', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '7a40d56f-0afb-4d6c-8ef2-a7719768932b'	System	14 Oct 2020 02:16:29
User entered '98.6'	System	14 Oct 2020 02:16:29

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:19:18

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-13T21:16:23', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '7a40d56f-0afb-4d6c-8ef2-a7719768932b'	System	14 Oct 2020 02:16:29
User entered 'No (N)'	System	14 Oct 2020 02:16:29

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:19:18
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-13T21:16:26', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '7a40d56f-0afb-4d6c-8ef2-a7719768932b'	System	14 Oct 2020 02:16:29
User entered '13 Oct 2020 21:16'	System	14 Oct 2020 02:16:29

US3912163

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:18

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '13 Oct 2020 14:56'	System	13 Oct 2020 16:54:17

US3912163

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:19:18

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	13 Oct 2020 16:54:17
User entered 'Day 2'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:19:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-14T12:15:44', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'b86a7b6c-deff-4544-946f-c667cf4414ef'	System	14 Oct 2020 17:15:59
User entered 'Yes (Y)'	System	14 Oct 2020 17:15:59

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:19:18

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-14T12:15:49', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'b86a7b6c-deff-4544-946f-c667cf4414ef'	System	14 Oct 2020 17:15:59
User entered '97.8'	System	14 Oct 2020 17:15:59

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:19:18
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-14T12:15:52', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'b86a7b6c-deff-4544-946f-c667cf4414ef'	System	14 Oct 2020 17:15:59
User entered 'No (N)'	System	14 Oct 2020 17:15:59

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:19:18
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-14T12:15:55', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'b86a7b6c-deff-4544-946f-c667cf4414ef'	System	14 Oct 2020 17:15:59
User entered '14 Oct 2020 12:15'	System	14 Oct 2020 17:15:59

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:19:18
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 16:54:17

US3912163

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:19:18

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	13 Oct 2020 16:54:17
User entered 'Day 3'	System	13 Oct 2020 16:54:17

US3912163

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-16T07:23:39', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '1ed5d86d-b154-4389-809e-e7be8f39c342'	System	16 Oct 2020 12:23:54
User entered 'Yes (Y)'	System	16 Oct 2020 12:23:54

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:19:18

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-16T07:23:45', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '1ed5d86d-b154-4389-809e-e7be8f39c342'	System	16 Oct 2020 12:23:54
User entered '97.6'	System	16 Oct 2020 12:23:54

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:19:18
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-16T07:23:49', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '1ed5d86d-b154-4389-809e-e7be8f39c342'	System	16 Oct 2020 12:23:54
User entered 'No (N)'	System	16 Oct 2020 12:23:54

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:19:18
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-16T07:23:52', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '1ed5d86d-b154-4389-809e-e7be8f39c342'	System	16 Oct 2020 12:23:54
User entered '16 Oct 2020 07:23'	System	16 Oct 2020 12:23:54

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:19:18
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 16:54:17

US3912163

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:19:18

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	13 Oct 2020 16:54:17
User entered 'Day 4'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:19:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-16T13:08:24', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'd0f77d29-532e-4b53-b0a4-4bd766b5c37c'	System	16 Oct 2020 18:08:40
User entered 'Yes (Y)'	System	16 Oct 2020 18:08:40

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:19:18

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-16T13:08:31', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'd0f77d29-532e-4b53-b0a4-4bd766b5c37c'	System	16 Oct 2020 18:08:40
User entered '97.8'	System	16 Oct 2020 18:08:40

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:19:18

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-16T13:08:34', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'd0f77d29-532e-4b53-b0a4-4bd766b5c37c'	System	16 Oct 2020 18:08:40
User entered 'No (N)'	System	16 Oct 2020 18:08:40

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:19:18
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-16T13:08:37', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'd0f77d29-532e-4b53-b0a4-4bd766b5c37c'	System	16 Oct 2020 18:08:40
User entered '16 Oct 2020 13:08'	System	16 Oct 2020 18:08:40

US3912163

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:18

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 16:54:17

US3912163

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:19:18

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	13 Oct 2020 16:54:17
User entered 'Day 5'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:19:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-17T12:00:18', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '2fad6601-af72-45c3-aa54-6b22f8b92a7d'	System	17 Oct 2020 17:01:17
User entered 'Yes (Y)'	System	17 Oct 2020 17:01:17

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:19:18

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-17T12:01:03', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '2fad6601-af72-45c3-aa54-6b22f8b92a7d'	System	17 Oct 2020 17:01:17
User entered '97.2'	System	17 Oct 2020 17:01:17

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:19:18
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-17T12:01:07', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '2fad6601-af72-45c3-aa54-6b22f8b92a7d'	System	17 Oct 2020 17:01:17
User entered 'No (N)'	System	17 Oct 2020 17:01:17

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:19:18

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-17T12:01:10', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '2fad6601-af72-45c3-aa54-6b22f8b92a7d'	System	17 Oct 2020 17:01:17
User entered '17 Oct 2020 12:01'	System	17 Oct 2020 17:01:17

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:19:18
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 16:54:17

US3912163

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:19:18

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	13 Oct 2020 16:54:17
User entered 'Day 6'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:19:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-18T12:26:26', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'df374bd4-9afa-4a7b-918d-1584c620a816'	System	18 Oct 2020 17:26:50
User entered 'Yes (Y)'	System	18 Oct 2020 17:26:50

US3912163

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:18

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-18T12:26:36', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'df374bd4-9afa-4a7b-918d-1584c620a816'	System	18 Oct 2020 17:26:50
User entered '97.8'	System	18 Oct 2020 17:26:50

US3912163

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:18

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-18T12:26:45', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'df374bd4-9afa-4a7b-918d-1584c620a816'	System	18 Oct 2020 17:26:50
User entered 'No (N)'	System	18 Oct 2020 17:26:50

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US3912163

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:18

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-18T12:26:47', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'df374bd4-9afa-4a7b-918d-1584c620a816'	System	18 Oct 2020 17:26:50
User entered '18 Oct 2020 12:26'	System	18 Oct 2020 17:26:50

US3912163

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:18

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 16:54:17

US3912163

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:19:18

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	13 Oct 2020 16:54:17
User entered 'Day 7'	System	13 Oct 2020 16:54:17

US3912163

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-19T12:12:35', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'e38ec3c0-796a-4445-8186-f2bb370dbab4'	System	19 Oct 2020 17:12:51
User entered 'Yes (Y)'	System	19 Oct 2020 17:12:51

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:19:18

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-19T12:12:41', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'e38ec3c0-796a-4445-8186-f2bb370dbab4'	System	19 Oct 2020 17:12:51
User entered '97.8'	System	19 Oct 2020 17:12:51

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:19:18
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-19T12:12:45', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'e38ec3c0-796a-4445-8186-f2bb370dbab4'	System	19 Oct 2020 17:12:51
User entered 'No (N)'	System	19 Oct 2020 17:12:51

US3912163
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:19:18
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-19T12:12:48', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'e38ec3c0-796a-4445-8186-f2bb370dbab4'	System	19 Oct 2020 17:12:51
User entered '19 Oct 2020 12:12'	System	19 Oct 2020 17:12:51

US3912163

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:18

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 16:54:17

US3912163

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:19:18

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	13 Oct 2020 16:54:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 16:54:17

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US3912163

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:18

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-13T11:58:37', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'bf0ce3d4-4c7f-4726-8ef1-65a2e7304f44'	System	13 Oct 2020 16:58:52
User entered 'None (1)'	System	13 Oct 2020 16:58:52

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:19:18
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-13T11:58:41', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'bf0ce3d4-4c7f-4726-8ef1-65a2e7304f44'	System	13 Oct 2020 16:58:52
User entered 'No (N)'	System	13 Oct 2020 16:58:52

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US3912163

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-13T11:58:44', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'bf0ce3d4-4c7f-4726-8ef1-65a2e7304f44'	System	13 Oct 2020 16:58:52
User entered 'No (N)'	System	13 Oct 2020 16:58:52

US3912163

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:19:18

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-13T11:58:46', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'bf0ce3d4-4c7f-4726-8ef1-65a2e7304f44'	System	13 Oct 2020 16:58:52
User entered 'None (1)'	System	13 Oct 2020 16:58:52

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:19:18
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-13T11:58:49', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'bf0ce3d4-4c7f-4726-8ef1-65a2e7304f44'	System	13 Oct 2020 16:58:52
User entered '13 Oct 2020 11:58'	System	13 Oct 2020 16:58:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '13 Oct 2020 11:31'	System	13 Oct 2020 16:54:17

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US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:19:18
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '13 Oct 2020 14:01'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	13 Oct 2020 16:54:17
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 16:54:17

US3912163

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:18

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-13T21:16:30', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '14abaf25-2302-44ea-a9f8-c7c576c6975e'	System	14 Oct 2020 02:17:05
User entered 'None (1)'	System	14 Oct 2020 02:17:05

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:19:18

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-13T21:16:34', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '14abaf25-2302-44ea-a9f8-c7c576c6975e'	System	14 Oct 2020 02:17:05
User entered 'No (N)'	System	14 Oct 2020 02:17:05

US3912163

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-13T21:16:38', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '14abaf25-2302-44ea-a9f8-c7c576c6975e'	System	14 Oct 2020 02:17:05
User entered 'No (N)'	System	14 Oct 2020 02:17:05

US3912163

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:19:18

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-13T21:16:45', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '14abaf25-2302-44ea-a9f8-c7c576c6975e'	System	14 Oct 2020 02:17:05
User entered 'None (1)'	System	14 Oct 2020 02:17:05

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:19:18
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-13T21:16:48', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '14abaf25-2302-44ea-a9f8-c7c576c6975e'	System	14 Oct 2020 02:17:05
User entered '13 Oct 2020 21:16'	System	14 Oct 2020 02:17:05

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:19:18
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '13 Oct 2020 14:56'	System	13 Oct 2020 16:54:17

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	13 Oct 2020 16:54:17
User entered 'Day 2'	System	13 Oct 2020 16:54:17

US3912163

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:18

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-14T12:15:59', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'c3ea80ec-ce0e-4b4e-8c8c-7752dd063811'	System	14 Oct 2020 17:16:11
User entered 'None (1)'	System	14 Oct 2020 17:16:11

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:19:18
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-14T12:16:02', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'c3ea80ec-ce0e-4b4e-8c8c-7752dd063811'	System	14 Oct 2020 17:16:11
User entered 'No (N)'	System	14 Oct 2020 17:16:11

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:19:18
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-14T12:16:05', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'c3ea80ec-ce0e-4b4e-8c8c-7752dd063811'	System	14 Oct 2020 17:16:11
User entered 'No (N)'	System	14 Oct 2020 17:16:11

US3912163

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:18

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-14T12:16:07', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'c3ea80ec-ce0e-4b4e-8c8c-7752dd063811'	System	14 Oct 2020 17:16:11
User entered 'None (1)'	System	14 Oct 2020 17:16:11

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:19:18
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-14T12:16:10', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'c3ea80ec-ce0e-4b4e-8c8c-7752dd063811'	System	14 Oct 2020 17:16:11
User entered '14 Oct 2020 12:16'	System	14 Oct 2020 17:16:11

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:19:18
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 16:54:17

US3912163

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:19:18

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	13 Oct 2020 16:54:17
User entered 'Day 3'	System	13 Oct 2020 16:54:17

US3912163

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:18

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-16T07:23:56', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'f28e8b59-1f3e-4778-aa72-40dad079f044'	System	16 Oct 2020 12:24:12
User entered 'None (1)'	System	16 Oct 2020 12:24:12

US3912163

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:18

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-16T07:24:01', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'f28e8b59-1f3e-4778-aa72-40dad079f044'	System	16 Oct 2020 12:24:12
User entered 'No (N)'	System	16 Oct 2020 12:24:12

US3912163

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-16T07:24:06', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'f28e8b59-1f3e-4778-aa72-40dad079f044'	System	16 Oct 2020 12:24:12
User entered 'No (N)'	System	16 Oct 2020 12:24:12

US3912163

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:19:18

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-16T07:24:08', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'f28e8b59-1f3e-4778-aa72-40dad079f044'	System	16 Oct 2020 12:24:12
User entered 'None (1)'	System	16 Oct 2020 12:24:12

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:19:18
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-16T07:24:11', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'f28e8b59-1f3e-4778-aa72-40dad079f044'	System	16 Oct 2020 12:24:12
User entered '16 Oct 2020 07:24'	System	16 Oct 2020 12:24:12

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:19:18
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 16:54:17

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 16:54:17

FDA-CBER-2022-1614-3509186

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	13 Oct 2020 16:54:17
User entered 'Day 4'	System	13 Oct 2020 16:54:17

FDA-CBER-2022-1614-3509187

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:19:18

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-16T13:08:40', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'cd87db56-20c8-4627-a9bd-84bdf167620f'	System	16 Oct 2020 18:08:52
User entered 'None (1)'	System	16 Oct 2020 18:08:52

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:19:18
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-16T13:08:43', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'cd87db56-20c8-4627-a9bd-84bdf167620f'	System	16 Oct 2020 18:08:52
User entered 'No (N)'	System	16 Oct 2020 18:08:52

US3912163

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-16T13:08:45', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'cd87db56-20c8-4627-a9bd-84bdf167620f'	System	16 Oct 2020 18:08:52
User entered 'No (N)'	System	16 Oct 2020 18:08:52

US3912163

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:18

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-16T13:08:47', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'cd87db56-20c8-4627-a9bd-84bdf167620f'	System	16 Oct 2020 18:08:52
User entered 'None (1)'	System	16 Oct 2020 18:08:52

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:19:18
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-16T13:08:49', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'cd87db56-20c8-4627-a9bd-84bdf167620f'	System	16 Oct 2020 18:08:52
User entered '16 Oct 2020 13:08'	System	16 Oct 2020 18:08:52

US3912163

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:19:18

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:19:18
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	13 Oct 2020 16:54:17
User entered 'Day 5'	System	13 Oct 2020 16:54:17

US3912163

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:18

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-17T12:01:14', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '9e50671f-4781-4512-9e17-155810aa7d07'	System	17 Oct 2020 17:01:28
User entered 'None (1)'	System	17 Oct 2020 17:01:28

US3912163

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:18

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-17T12:01:17', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '9e50671f-4781-4512-9e17-155810aa7d07'	System	17 Oct 2020 17:01:28
User entered 'No (N)'	System	17 Oct 2020 17:01:28

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:19:18
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-17T12:01:19', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '9e50671f-4781-4512-9e17-155810aa7d07'	System	17 Oct 2020 17:01:28
User entered 'No (N)'	System	17 Oct 2020 17:01:28

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US3912163

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:19:18

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-17T12:01:21', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '9e50671f-4781-4512-9e17-155810aa7d07'	System	17 Oct 2020 17:01:28
User entered 'None (1)'	System	17 Oct 2020 17:01:28

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:19:18
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-17T12:01:24', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '9e50671f-4781-4512-9e17-155810aa7d07'	System	17 Oct 2020 17:01:28
User entered '17 Oct 2020 12:01'	System	17 Oct 2020 17:01:28

FDA-CBER-2022-1614-3509200

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:19:18
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:19:18
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	13 Oct 2020 16:54:17
User entered 'Day 6'	System	13 Oct 2020 16:54:17

US3912163

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:18

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-18T12:26:51', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '554815d5-0214-452c-8bf4-1c8709bb812d'	System	18 Oct 2020 17:27:06
User entered 'None (1)'	System	18 Oct 2020 17:27:06

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US3912163

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:19:18

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-18T12:26:54', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '554815d5-0214-452c-8bf4-1c8709bb812d'	System	18 Oct 2020 17:27:06
User entered 'No (N)'	System	18 Oct 2020 17:27:06

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:19:18
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-18T12:26:57', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '554815d5-0214-452c-8bf4-1c8709bb812d'	System	18 Oct 2020 17:27:06
User entered 'No (N)'	System	18 Oct 2020 17:27:06

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:19:18

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-18T12:27:00', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '554815d5-0214-452c-8bf4-1c8709bb812d'	System	18 Oct 2020 17:27:06
User entered 'None (1)'	System	18 Oct 2020 17:27:06

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:19:18
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-18T12:27:04', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '554815d5-0214-452c-8bf4-1c8709bb812d'	System	18 Oct 2020 17:27:06
User entered '18 Oct 2020 12:27'	System	18 Oct 2020 17:27:06

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:19:18

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:19:18
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	13 Oct 2020 16:54:17
User entered 'Day 7'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:19:18

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-19T12:12:51', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '71e1654e-f605-486a-b0f2-31c81f93392d'	System	19 Oct 2020 17:13:04
User entered 'None (1)'	System	19 Oct 2020 17:13:04

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:19:18
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-19T12:12:54', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '71e1654e-f605-486a-b0f2-31c81f93392d'	System	19 Oct 2020 17:13:04
User entered 'No (N)'	System	19 Oct 2020 17:13:04

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:19:18
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-19T12:12:57', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '71e1654e-f605-486a-b0f2-31c81f93392d'	System	19 Oct 2020 17:13:04
User entered 'No (N)'	System	19 Oct 2020 17:13:04

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US3912163

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:19:18

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-19T12:12:58', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '71e1654e-f605-486a-b0f2-31c81f93392d'	System	19 Oct 2020 17:13:04
User entered 'None (1)'	System	19 Oct 2020 17:13:04

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:19:18
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-19T12:13:01', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '71e1654e-f605-486a-b0f2-31c81f93392d'	System	19 Oct 2020 17:13:04
User entered '19 Oct 2020 12:13'	System	19 Oct 2020 17:13:04

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:19:18
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:19:18
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	13 Oct 2020 16:54:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:19:18
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-13T11:58:52', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '01bc79f4-3e98-40a9-9bd2-4cbe8c0d0c15'	System	13 Oct 2020 16:59:14
User entered 'None (0)'	System	13 Oct 2020 16:59:14

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:19:18
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-13T11:58:54', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '01bc79f4-3e98-40a9-9bd2-4cbe8c0d0c15'	System	13 Oct 2020 16:59:14
User entered 'None (0)'	System	13 Oct 2020 16:59:14

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:19:18
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-13T11:58:56', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '01bc79f4-3e98-40a9-9bd2-4cbe8c0d0c15'	System	13 Oct 2020 16:59:14
User entered 'None (0)'	System	13 Oct 2020 16:59:14

US3912163

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-13T11:58:58', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '01bc79f4-3e98-40a9-9bd2-4cbe8c0d0c15'	System	13 Oct 2020 16:59:14
User entered 'None (0)'	System	13 Oct 2020 16:59:14

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:19:18
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-13T11:59:00', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '01bc79f4-3e98-40a9-9bd2-4cbe8c0d0c15'	System	13 Oct 2020 16:59:14
User entered 'None (0)'	System	13 Oct 2020 16:59:14

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:19:18
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-13T11:59:02', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '01bc79f4-3e98-40a9-9bd2-4cbe8c0d0c15'	System	13 Oct 2020 16:59:14
User entered 'None (0)'	System	13 Oct 2020 16:59:14

US3912163

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:18

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-13T11:59:08', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '01bc79f4-3e98-40a9-9bd2-4cbe8c0d0c15'	System	13 Oct 2020 16:59:14
User entered 'No (N)'	System	13 Oct 2020 16:59:14

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:19:18
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-13T11:59:12', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '01bc79f4-3e98-40a9-9bd2-4cbe8c0d0c15'	System	13 Oct 2020 16:59:14
User entered '13 Oct 2020 11:59'	System	13 Oct 2020 16:59:14

US3912163

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:18

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '13 Oct 2020 11:31'	System	13 Oct 2020 16:54:17

US3912163

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:19:18

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '13 Oct 2020 14:01'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	13 Oct 2020 16:54:17
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:19:18
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-13T21:16:52', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '05af1d36-dc0d-49b7-a4c3-af91a09e4c69'	System	14 Oct 2020 02:17:20
User entered 'None (0)'	System	14 Oct 2020 02:17:20

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:19:18
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-13T21:16:58', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '05af1d36-dc0d-49b7-a4c3-af91a09e4c69'	System	14 Oct 2020 02:17:20
User entered 'No interference with activity (1)'	System	14 Oct 2020 02:17:20

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:19:18
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-13T21:17:00', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '05af1d36-dc0d-49b7-a4c3-af91a09e4c69'	System	14 Oct 2020 02:17:20
User entered 'None (0)'	System	14 Oct 2020 02:17:20

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:19:18
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-13T21:17:02', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '05af1d36-dc0d-49b7-a4c3-af91a09e4c69'	System	14 Oct 2020 02:17:20
User entered 'None (0)'	System	14 Oct 2020 02:17:20

US3912163

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-13T21:17:04', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '05af1d36-dc0d-49b7-a4c3-af91a09e4c69'	System	14 Oct 2020 02:17:20
User entered 'None (0)'	System	14 Oct 2020 02:17:20

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:19:18
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-13T21:17:07', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '05af1d36-dc0d-49b7-a4c3-af91a09e4c69'	System	14 Oct 2020 02:17:20
User entered 'None (0)'	System	14 Oct 2020 02:17:20

US3912163

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:18

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-13T21:17:11', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '05af1d36-dc0d-49b7-a4c3-af91a09e4c69'	System	14 Oct 2020 02:17:20
User entered 'No (N)'	System	14 Oct 2020 02:17:20

US3912163

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:18

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-13T21:17:13', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '05af1d36-dc0d-49b7-a4c3-af91a09e4c69'	System	14 Oct 2020 02:17:20
User entered '13 Oct 2020 21:17'	System	14 Oct 2020 02:17:20

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '13 Oct 2020 14:56'	System	13 Oct 2020 16:54:17

US3912163

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:19:18

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	13 Oct 2020 16:54:17
User entered 'Day 2'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:19:18
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-14T12:16:15', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '0563ecf9-eb78-4e32-8a68-34ef827b3094'	System	14 Oct 2020 17:16:37
User entered 'None (0)'	System	14 Oct 2020 17:16:37

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:19:18
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-14T12:16:20', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '0563ecf9-eb78-4e32-8a68-34ef827b3094'	System	14 Oct 2020 17:16:37
User entered 'None (0)'	System	14 Oct 2020 17:16:37

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:19:18
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-14T12:16:23', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '0563ecf9-eb78-4e32-8a68-34ef827b3094'	System	14 Oct 2020 17:16:37
User entered 'None (0)'	System	14 Oct 2020 17:16:37

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:19:18
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-14T12:16:25', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '0563ecf9-eb78-4e32-8a68-34ef827b3094'	System	14 Oct 2020 17:16:37
User entered 'None (0)'	System	14 Oct 2020 17:16:37

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:19:18
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-14T12:16:27', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '0563ecf9-eb78-4e32-8a68-34ef827b3094'	System	14 Oct 2020 17:16:37
User entered 'None (0)'	System	14 Oct 2020 17:16:37

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:19:18
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-14T12:16:29', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '0563ecf9-eb78-4e32-8a68-34ef827b3094'	System	14 Oct 2020 17:16:37
User entered 'None (0)'	System	14 Oct 2020 17:16:37

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:19:18

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-14T12:16:33', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '0563ecf9-eb78-4e32-8a68-34ef827b3094'	System	14 Oct 2020 17:16:37
User entered 'No (N)'	System	14 Oct 2020 17:16:37

US3912163

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:18

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-14T12:16:35', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '0563ecf9-eb78-4e32-8a68-34ef827b3094'	System	14 Oct 2020 17:16:37
User entered '14 Oct 2020 12:16'	System	14 Oct 2020 17:16:37

US3912163

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:18

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 16:54:17

US3912163

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:19:18

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	13 Oct 2020 16:54:17
User entered 'Day 3'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:19:18
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-16T07:24:15', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'bae6c92d-9e6a-46c1-9672-7560c0c6dd15'	System	16 Oct 2020 12:24:34
User entered 'None (0)'	System	16 Oct 2020 12:24:34

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:19:18
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-16T07:24:17', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'bae6c92d-9e6a-46c1-9672-7560c0c6dd15'	System	16 Oct 2020 12:24:34
User entered 'None (0)'	System	16 Oct 2020 12:24:34

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:19:18
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-16T07:24:20', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'bae6c92d-9e6a-46c1-9672-7560c0c6dd15'	System	16 Oct 2020 12:24:34
User entered 'None (0)'	System	16 Oct 2020 12:24:34

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:19:18
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-16T07:24:22', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'bae6c92d-9e6a-46c1-9672-7560c0c6dd15'	System	16 Oct 2020 12:24:34
User entered 'None (0)'	System	16 Oct 2020 12:24:34

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:19:18
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-16T07:24:24', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'bae6c92d-9e6a-46c1-9672-7560c0c6dd15'	System	16 Oct 2020 12:24:34
User entered 'None (0)'	System	16 Oct 2020 12:24:34

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:19:18
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-16T07:24:26', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'bae6c92d-9e6a-46c1-9672-7560c0c6dd15'	System	16 Oct 2020 12:24:34
User entered 'None (0)'	System	16 Oct 2020 12:24:34

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:19:18

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-16T07:24:31', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'bae6c92d-9e6a-46c1-9672-7560c0c6dd15'	System	16 Oct 2020 12:24:34
User entered 'No (N)'	System	16 Oct 2020 12:24:34

US3912163

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:18

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-16T07:24:33', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'bae6c92d-9e6a-46c1-9672-7560c0c6dd15'	System	16 Oct 2020 12:24:34
User entered '16 Oct 2020 07:24'	System	16 Oct 2020 12:24:34

US3912163

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:18

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 16:54:17

US3912163

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:19:18

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	13 Oct 2020 16:54:17
User entered 'Day 4'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:19:18
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-16T13:08:52', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'c8f139f4-c2cc-45e4-832e-7625952eb97a'	System	16 Oct 2020 18:09:17
User entered 'None (0)'	System	16 Oct 2020 18:09:17

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:19:18
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-16T13:08:54', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'c8f139f4-c2cc-45e4-832e-7625952eb97a'	System	16 Oct 2020 18:09:17
User entered 'None (0)'	System	16 Oct 2020 18:09:17

US3912163

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-16T13:08:55', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'c8f139f4-c2cc-45e4-832e-7625952eb97a'	System	16 Oct 2020 18:09:17
User entered 'None (0)'	System	16 Oct 2020 18:09:17

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:19:18
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-16T13:08:57', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'c8f139f4-c2cc-45e4-832e-7625952eb97a'	System	16 Oct 2020 18:09:17
User entered 'None (0)'	System	16 Oct 2020 18:09:17

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:19:18
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-16T13:08:59', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'c8f139f4-c2cc-45e4-832e-7625952eb97a'	System	16 Oct 2020 18:09:17
User entered 'None (0)'	System	16 Oct 2020 18:09:17

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:19:18
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-16T13:09:01', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'c8f139f4-c2cc-45e4-832e-7625952eb97a'	System	16 Oct 2020 18:09:17
User entered 'None (0)'	System	16 Oct 2020 18:09:17

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:19:18

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-16T13:09:04', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'c8f139f4-c2cc-45e4-832e-7625952eb97a'	System	16 Oct 2020 18:09:17
User entered 'No (N)'	System	16 Oct 2020 18:09:17

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:19:18
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-16T13:09:06', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'c8f139f4-c2cc-45e4-832e-7625952eb97a'	System	16 Oct 2020 18:09:17
User entered '16 Oct 2020 13:09'	System	16 Oct 2020 18:09:17

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 16:54:17

US3912163

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:19:18

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	13 Oct 2020 16:54:17
User entered 'Day 5'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:19:18
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-17T12:01:27', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'df5a88ac-4198-45f2-b46e-6cb3f4eac535'	System	17 Oct 2020 17:01:44
User entered 'None (0)'	System	17 Oct 2020 17:01:44

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:19:18
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-17T12:01:28', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'df5a88ac-4198-45f2-b46e-6cb3f4eac535'	System	17 Oct 2020 17:01:44
User entered 'None (0)'	System	17 Oct 2020 17:01:44

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:19:18
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-17T12:01:30', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'df5a88ac-4198-45f2-b46e-6cb3f4eac535'	System	17 Oct 2020 17:01:44
User entered 'None (0)'	System	17 Oct 2020 17:01:44

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:19:18
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-17T12:01:34', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'df5a88ac-4198-45f2-b46e-6cb3f4eac535'	System	17 Oct 2020 17:01:44
User entered 'None (0)'	System	17 Oct 2020 17:01:44

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:19:18
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-17T12:01:36', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'df5a88ac-4198-45f2-b46e-6cb3f4eac535'	System	17 Oct 2020 17:01:44
User entered 'None (0)'	System	17 Oct 2020 17:01:44

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:19:18
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-17T12:01:38', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'df5a88ac-4198-45f2-b46e-6cb3f4eac535'	System	17 Oct 2020 17:01:44
User entered 'None (0)'	System	17 Oct 2020 17:01:44

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:19:18
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-17T12:01:41', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'df5a88ac-4198-45f2-b46e-6cb3f4eac535'	System	17 Oct 2020 17:01:44
User entered 'No (N)'	System	17 Oct 2020 17:01:44

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:19:18
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-17T12:01:43', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'df5a88ac-4198-45f2-b46e-6cb3f4eac535'	System	17 Oct 2020 17:01:44
User entered '17 Oct 2020 12:01'	System	17 Oct 2020 17:01:44

US3912163

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:18

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 16:54:17

US3912163

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:19:18

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	13 Oct 2020 16:54:17
User entered 'Day 6'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:19:18
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-18T12:27:07', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '82d7a519-9f67-47a1-b8e5-a230a43b6ab4'	System	18 Oct 2020 17:27:23
User entered 'None (0)'	System	18 Oct 2020 17:27:23

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:19:18
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-18T12:27:09', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '82d7a519-9f67-47a1-b8e5-a230a43b6ab4'	System	18 Oct 2020 17:27:23
User entered 'None (0)'	System	18 Oct 2020 17:27:23

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:19:18
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-18T12:27:11', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '82d7a519-9f67-47a1-b8e5-a230a43b6ab4'	System	18 Oct 2020 17:27:23
User entered 'None (0)'	System	18 Oct 2020 17:27:23

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:19:18
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-18T12:27:13', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '82d7a519-9f67-47a1-b8e5-a230a43b6ab4'	System	18 Oct 2020 17:27:23
User entered 'None (0)'	System	18 Oct 2020 17:27:23

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:19:18
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-18T12:27:14', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '82d7a519-9f67-47a1-b8e5-a230a43b6ab4'	System	18 Oct 2020 17:27:23
User entered 'None (0)'	System	18 Oct 2020 17:27:23

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:19:18
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-18T12:27:16', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '82d7a519-9f67-47a1-b8e5-a230a43b6ab4'	System	18 Oct 2020 17:27:23
User entered 'None (0)'	System	18 Oct 2020 17:27:23

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:19:18
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-18T12:27:20', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '82d7a519-9f67-47a1-b8e5-a230a43b6ab4'	System	18 Oct 2020 17:27:23
User entered 'No (N)'	System	18 Oct 2020 17:27:23

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US3912163

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:19:18

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-18T12:27:22', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '82d7a519-9f67-47a1-b8e5-a230a43b6ab4'	System	18 Oct 2020 17:27:23
User entered '18 Oct 2020 12:27'	System	18 Oct 2020 17:27:23

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:19:18
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:19:18
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
Data entry locked.	System	13 Oct 2020 16:54:17
User entered 'Day 7'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:19:18
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-19T12:13:04', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '9b55c4bc-5597-4189-bc78-7b476e2f5f92'	System	19 Oct 2020 17:13:20
User entered 'None (0)'	System	19 Oct 2020 17:13:20

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:19:18
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-19T12:13:06', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '9b55c4bc-5597-4189-bc78-7b476e2f5f92'	System	19 Oct 2020 17:13:20
User entered 'None (0)'	System	19 Oct 2020 17:13:20

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:19:18
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-19T12:13:07', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '9b55c4bc-5597-4189-bc78-7b476e2f5f92'	System	19 Oct 2020 17:13:20
User entered 'None (0)'	System	19 Oct 2020 17:13:20

US3912163

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-19T12:13:09', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '9b55c4bc-5597-4189-bc78-7b476e2f5f92'	System	19 Oct 2020 17:13:20
User entered 'None (0)'	System	19 Oct 2020 17:13:20

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:19:18
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-19T12:13:10', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '9b55c4bc-5597-4189-bc78-7b476e2f5f92'	System	19 Oct 2020 17:13:20
User entered 'None (0)'	System	19 Oct 2020 17:13:20

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:19:18
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-19T12:13:12', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '9b55c4bc-5597-4189-bc78-7b476e2f5f92'	System	19 Oct 2020 17:13:20
User entered 'None (0)'	System	19 Oct 2020 17:13:20

US3912163

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:18

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-19T12:13:15', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '9b55c4bc-5597-4189-bc78-7b476e2f5f92'	System	19 Oct 2020 17:13:20
User entered 'No (N)'	System	19 Oct 2020 17:13:20

US3912163

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:19:18

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-10-19T12:13:18', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '9b55c4bc-5597-4189-bc78-7b476e2f5f92'	System	19 Oct 2020 17:13:20
User entered '19 Oct 2020 12:13'	System	19 Oct 2020 17:13:20

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:19:18
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 16:54:17

US3912163
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:19:18
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:27:18
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 16:54:17

US3912163

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:18

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Amy Collins (b) (4) (b) (4)	20 Oct 2020 17:17:55

US3912163

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:18

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '20 Oct 2020'	Amy Collins (b) (4) (b) (4)	20 Oct 2020 17:17:55

US3912163

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:18

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Contact Made (CONTACT MADE)'	Amy Collins (b) (4) (b) (4)	20 Oct 2020 17:17:55

US3912163
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:19:18
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered empty.	Amy Collins (b) (4) (b) (4)	20 Oct 2020 17:17:55

US3912163
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:19:18

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Amy Collins (b) (4) (b) (4)	20 Oct 2020 17:18:06

US3912163
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:19:18
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered '1'	System	20 Oct 2020 17:18:06

US3912163
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:19:18

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	28 Oct 2020 16:22:34

US3912163
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:19:18

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '28 Oct 2020'	Mia Rountree (b) (4) (b) (4)	28 Oct 2020 16:22:34

US3912163

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:18

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Contact Made (CONTACT MADE)'	Mia Rountree (b) (4) (b) (4)	28 Oct 2020 16:22:34

US3912163

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:18

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered empty.	Mia Rountree (b) (4) (b) (4)	28 Oct 2020 16:22:34

US3912163

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:18

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	28 Oct 2020 16:22:42

US3912163
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:19:18
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered '1'	System	28 Oct 2020 16:22:42

US3912163

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:18

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Amy Collins (b) (4) (b) (4)	04 Nov 2020 00:31:46

US3912163

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:18

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '03 Nov 2020'	Amy Collins (b) (4) (b) (4)	04 Nov 2020 00:31:46

US3912163

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:18

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Contact Made (CONTACT MADE)'	Amy Collins (b) (4) (b) (4)	04 Nov 2020 00:31:46

US3912163

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:18

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered empty.	Amy Collins (b) (4) (b) (4)	04 Nov 2020 00:31:46

US3912163

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:18

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Amy Collins (b) (4) (b) (4)	04 Nov 2020 00:31:54

US3912163
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:19:18
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered '1'	System	04 Nov 2020 00:31:54

US3912163
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:19:18
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	14 Dec 2020 18:50:54

US3912163
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:19:18
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered empty.	Sandra Clancy (b) (4) (b) (4)	14 Dec 2020 18:50:54

US3912163

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:19:18

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered empty.	Sandra Clancy (b) (4) (b) (4)	14 Dec 2020 18:50:54

US3912163
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:19:18
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered 'VISIT3'	System	14 Dec 2020 18:50:54

US3912163

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:18

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	14 Dec 2020 18:50:46

US3912163
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:19:18
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered '1'	System	14 Dec 2020 18:50:46

US3912163

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:07:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:37:23
Data entry locked.	System	15 Sep 2020 16:44:57
User entered 'Day 64'	System	15 Sep 2020 16:44:57

US3912163

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:07:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:37:23

US3912163

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:07:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:37:23

US3912163

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:07:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:37:23

US3912163

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:07:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:37:23

US3912163
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:07:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:37:23

US3912163
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:07:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:37:23

US3912163

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:07:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:37:23

US3912163

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:07:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:37:23

US3912163
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:07:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:37:23

US3912163
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:07:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:37:23

US3912163
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:07:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:37:23

US3912163

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:07:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:37:23

US3912163
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:07:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:37:23

US3912163
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:07:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:37:23

US3912163
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:07:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:37:23

US3912163
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:07:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:37:23

FDA-CBER-2022-1614-3509347

US3912163

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:07:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:37:23

US3912163

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:07:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:37:23

US3912163
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:07:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:37:23

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:07:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:37:23

FDA-CBER-2022-1614-3509351

US3912163
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:07:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:37:23

FDA-CBER-2022-1614-3509352

US3912163

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:07:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:37:23

US3912163

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:07:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:37:23

US3912163

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:07:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:37:23

US3912163

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:07:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:37:23

US3912163

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:07:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:37:23
Data entry locked.	System	15 Sep 2020 16:44:57
User entered '15 Nov 2020 00:01'	System	15 Sep 2020 16:44:57

US3912163

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:07:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:37:23
Data entry locked.	System	15 Sep 2020 16:44:57
User entered '19 Nov 2020 23:59'	System	15 Sep 2020 16:44:57

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 08:37:23

FDA-CBER-2022-1614-3509359

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-12-07T10:44:08', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'b67b0e93-681c-485b-9464-7e1ebd499fe4'	System	07 Dec 2020 16:44:21
User entered 'No (N)'	System	07 Dec 2020 16:44:21

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-12-07T10:44:16', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'b67b0e93-681c-485b-9464-7e1ebd499fe4'	System	07 Dec 2020 16:44:21
User entered 'No (N)'	System	07 Dec 2020 16:44:21

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-12-07T10:44:19', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'b67b0e93-681c-485b-9464-7e1ebd499fe4'	System	07 Dec 2020 16:44:21
User entered '07 Dec 2020 10:44:19'	System	07 Dec 2020 16:44:21

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 08:37:23

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 08:37:23

FDA-CBER-2022-1614-3509371

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-12-11T16:19:17', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '5f1c18bc-67d2-4606-8492-fd71647089d5'	System	11 Dec 2020 22:20:31
User entered 'Yes (Y)'	System	11 Dec 2020 22:20:31

FDA-CBER-2022-1614-3509372

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-12-11T16:19:28', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '5f1c18bc-67d2-4606-8492-fd71647089d5'	System	11 Dec 2020 22:20:31
User entered 'No (N)'	System	11 Dec 2020 22:20:31

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-12-11T16:19:36', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '5f1c18bc-67d2-4606-8492-fd71647089d5'	System	11 Dec 2020 22:20:31
User entered 'Yes (Y)'	System	11 Dec 2020 22:20:31

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-12-11T16:19:51', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '5f1c18bc-67d2-4606-8492-fd71647089d5'	System	11 Dec 2020 22:20:31
User entered '0'	System	11 Dec 2020 22:20:31

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Chills

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-12-11T16:19:51', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '5f1c18bc-67d2-4606-8492-fd71647089d5'	System	11 Dec 2020 22:20:31
User entered '0'	System	11 Dec 2020 22:20:31

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Cough

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-12-11T16:19:51', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '5f1c18bc-67d2-4606-8492-fd71647089d5'	System	11 Dec 2020 22:20:31
User entered '1'	System	11 Dec 2020 22:20:31

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Shortness of breath

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-12-11T16:19:51', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '5f1c18bc-67d2-4606-8492-fd71647089d5'	System	11 Dec 2020 22:20:31
User entered '0'	System	11 Dec 2020 22:20:31

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Difficulty breathing

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-12-11T16:19:51', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '5f1c18bc-67d2-4606-8492-fd71647089d5'	System	11 Dec 2020 22:20:31
User entered '0'	System	11 Dec 2020 22:20:31

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Fatigue

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-12-11T16:19:51', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '5f1c18bc-67d2-4606-8492-fd71647089d5'	System	11 Dec 2020 22:20:31
User entered '1'	System	11 Dec 2020 22:20:31

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Muscle aches

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-12-11T16:19:51', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '5f1c18bc-67d2-4606-8492-fd71647089d5'	System	11 Dec 2020 22:20:31
User entered '0'	System	11 Dec 2020 22:20:31

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18

Body aches

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-12-11T16:19:51', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '5f1c18bc-67d2-4606-8492-fd71647089d5'	System	11 Dec 2020 22:20:31
User entered '0'	System	11 Dec 2020 22:20:31

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Headache

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-12-11T16:19:51', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '5f1c18bc-67d2-4606-8492-fd71647089d5'	System	11 Dec 2020 22:20:31
User entered '0'	System	11 Dec 2020 22:20:31

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

New loss of taste

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-12-11T16:19:51', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '5f1c18bc-67d2-4606-8492-fd71647089d5'	System	11 Dec 2020 22:20:31
User entered '0'	System	11 Dec 2020 22:20:31

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

New loss of smell

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-12-11T16:19:51', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '5f1c18bc-67d2-4606-8492-fd71647089d5'	System	11 Dec 2020 22:20:31
User entered '0'	System	11 Dec 2020 22:20:31

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18

Sore throat

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-12-11T16:19:51', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '5f1c18bc-67d2-4606-8492-fd71647089d5'	System	11 Dec 2020 22:20:31
User entered '0'	System	11 Dec 2020 22:20:31

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Congestion

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-12-11T16:19:51', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '5f1c18bc-67d2-4606-8492-fd71647089d5'	System	11 Dec 2020 22:20:31
User entered '1'	System	11 Dec 2020 22:20:31

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18

Runny nose

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-12-11T16:19:51', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '5f1c18bc-67d2-4606-8492-fd71647089d5'	System	11 Dec 2020 22:20:31
User entered '0'	System	11 Dec 2020 22:20:31

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Nausea

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-12-11T16:19:51', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '5f1c18bc-67d2-4606-8492-fd71647089d5'	System	11 Dec 2020 22:20:31
User entered '0'	System	11 Dec 2020 22:20:31

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18

Vomiting

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-12-11T16:19:51', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '5f1c18bc-67d2-4606-8492-fd71647089d5'	System	11 Dec 2020 22:20:31
User entered '0'	System	11 Dec 2020 22:20:31

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Diarrhea

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-12-11T16:19:51', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '5f1c18bc-67d2-4606-8492-fd71647089d5'	System	11 Dec 2020 22:20:31
User entered '0'	System	11 Dec 2020 22:20:31

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-12-11T16:19:59', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '5f1c18bc-67d2-4606-8492-fd71647089d5'	System	11 Dec 2020 22:20:31
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Dec 2020 22:20:31

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-12-11T16:20:12', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '5f1c18bc-67d2-4606-8492-fd71647089d5'	System	11 Dec 2020 22:20:31
User entered 'No (N)'	System	11 Dec 2020 22:20:31

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-12-11T16:20:19', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '5f1c18bc-67d2-4606-8492-fd71647089d5'	System	11 Dec 2020 22:20:31
User entered '11 Dec 2020 16:20:19'	System	11 Dec 2020 22:20:31

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 08:37:23

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-12-19T14:58:29', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'c4e5a6d7-46a2-4d94-873f-8312e8f8e32b'	System	19 Dec 2020 20:58:42
User entered 'No (N)'	System	19 Dec 2020 20:58:42

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-12-19T14:58:36', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'c4e5a6d7-46a2-4d94-873f-8312e8f8e32b'	System	19 Dec 2020 20:58:42
User entered 'No (N)'	System	19 Dec 2020 20:58:42

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-12-19T14:58:39', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'c4e5a6d7-46a2-4d94-873f-8312e8f8e32b'	System	19 Dec 2020 20:58:42
User entered '19 Dec 2020 14:58:39'	System	19 Dec 2020 20:58:42

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-12-28T12:43:58', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'b671b283-044e-4042-9992-a0fed44fb6a0'	System	28 Dec 2020 18:44:10
User entered 'No (N)'	System	28 Dec 2020 18:44:10

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-12-28T12:44:03', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'b671b283-044e-4042-9992-a0fed44fb6a0'	System	28 Dec 2020 18:44:10
User entered 'No (N)'	System	28 Dec 2020 18:44:10

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-12-28T12:44:07', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'b671b283-044e-4042-9992-a0fed44fb6a0'	System	28 Dec 2020 18:44:10
User entered '28 Dec 2020 12:44:07'	System	28 Dec 2020 18:44:10

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-12-31T14:23:33', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'f5dec7fe-c8f5-4240-8620-f45338f3b8c2'	System	31 Dec 2020 20:23:47
User entered 'No (N)'	System	31 Dec 2020 20:23:47

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-12-31T14:23:37', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'f5dec7fe-c8f5-4240-8620-f45338f3b8c2'	System	31 Dec 2020 20:23:47
User entered 'No (N)'	System	31 Dec 2020 20:23:47

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2020-12-31T14:23:42', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'f5dec7fe-c8f5-4240-8620-f45338f3b8c2'	System	31 Dec 2020 20:23:47
User entered '31 Dec 2020 14:23:42'	System	31 Dec 2020 20:23:47

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 08:37:23

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 08:37:23

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US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-01-07T11:01:30', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'd2724be1-33c3-4e8a-bcbf-734f7073f12d'	System	07 Jan 2021 17:01:43
User entered 'No (N)'	System	07 Jan 2021 17:01:43

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-01-07T11:01:33', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'd2724be1-33c3-4e8a-bcbf-734f7073f12d'	System	07 Jan 2021 17:01:43
User entered 'No (N)'	System	07 Jan 2021 17:01:43

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-01-07T11:01:37', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'd2724be1-33c3-4e8a-bcbf-734f7073f12d'	System	07 Jan 2021 17:01:43
User entered '07 Jan 2021 11:01:37'	System	07 Jan 2021 17:01:43

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-01-14T00:01:58', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'bd902e8b-dbdc-4028-a191-71ad25a74b3a'	System	14 Jan 2021 06:02:11
User entered 'No (N)'	System	14 Jan 2021 06:02:11

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-01-14T00:02:02', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'bd902e8b-dbdc-4028-a191-71ad25a74b3a'	System	14 Jan 2021 06:02:11
User entered 'No (N)'	System	14 Jan 2021 06:02:11

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-01-14T00:02:07', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'bd902e8b-dbdc-4028-a191-71ad25a74b3a'	System	14 Jan 2021 06:02:11
User entered '14 Jan 2021 00:02:07'	System	14 Jan 2021 06:02:11

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-01-21T07:21:11', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '8da8c9f8-e1be-4852-897f-4a4f4a50e391'	System	21 Jan 2021 13:21:23
User entered 'No (N)'	System	21 Jan 2021 13:21:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-01-21T07:21:16', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '8da8c9f8-e1be-4852-897f-4a4f4a50e391'	System	21 Jan 2021 13:21:23
User entered 'No (N)'	System	21 Jan 2021 13:21:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-01-21T07:21:20', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '8da8c9f8-e1be-4852-897f-4a4f4a50e391'	System	21 Jan 2021 13:21:23
User entered '21 Jan 2021 07:21:20'	System	21 Jan 2021 13:21:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-01-28T18:40:53', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'd99f248c-3da7-4d7e-980f-0cce94e0723f'	System	29 Jan 2021 00:41:02
User entered 'No (N)'	System	29 Jan 2021 00:41:02

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-01-28T18:40:57', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'd99f248c-3da7-4d7e-980f-0cce94e0723f'	System	29 Jan 2021 00:41:02
User entered 'No (N)'	System	29 Jan 2021 00:41:02

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-01-28T18:41:00', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'd99f248c-3da7-4d7e-980f-0cce94e0723f'	System	29 Jan 2021 00:41:02
User entered '28 Jan 2021 18:41:00'	System	29 Jan 2021 00:41:02

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 08:37:23

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 08:37:23

FDA-CBER-2022-1614-3509439

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-02-04T07:54:53', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '1d969322-b7d6-4d94-8797-8948bac34451'	System	04 Feb 2021 13:55:36
User entered 'Yes (Y)'	System	04 Feb 2021 13:55:36

FDA-CBER-2022-1614-3509440

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-02-04T07:54:58', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '1d969322-b7d6-4d94-8797-8948bac34451'	System	04 Feb 2021 13:55:36
User entered 'No (N)'	System	04 Feb 2021 13:55:36

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-02-04T07:55:05', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '1d969322-b7d6-4d94-8797-8948bac34451'	System	04 Feb 2021 13:55:36
User entered 'No (N)'	System	04 Feb 2021 13:55:36

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-02-04T07:55:13', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '1d969322-b7d6-4d94-8797-8948bac34451'	System	04 Feb 2021 13:55:36
User entered 'Yes (Y)'	System	04 Feb 2021 13:55:36

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-02-04T07:55:22', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '1d969322-b7d6-4d94-8797-8948bac34451'	System	04 Feb 2021 13:55:36
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Feb 2021 13:55:36

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-02-04T07:55:26', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '1d969322-b7d6-4d94-8797-8948bac34451'	System	04 Feb 2021 13:55:36
User entered '04 Feb 2021 07:55:26'	System	04 Feb 2021 13:55:36

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-02-11T14:38:31', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'f76ca69d-e08b-4d0a-b2de-c7a6eb56f7ae'	System	11 Feb 2021 20:38:41
User entered 'No (N)'	System	11 Feb 2021 20:38:41

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-02-11T14:38:34', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'f76ca69d-e08b-4d0a-b2de-c7a6eb56f7ae'	System	11 Feb 2021 20:38:41
User entered 'No (N)'	System	11 Feb 2021 20:38:41

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-02-11T14:38:37', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'f76ca69d-e08b-4d0a-b2de-c7a6eb56f7ae'	System	11 Feb 2021 20:38:41
User entered '11 Feb 2021 14:38:37'	System	11 Feb 2021 20:38:41

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-02-18T07:46:43', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '072c115b-13a8-436b-b0b9-2a1a04dbf8ac'	System	18 Feb 2021 13:46:54
User entered 'No (N)'	System	18 Feb 2021 13:46:54

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-02-18T07:46:46', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '072c115b-13a8-436b-b0b9-2a1a04dbf8ac'	System	18 Feb 2021 13:46:54
User entered 'No (N)'	System	18 Feb 2021 13:46:54

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-02-18T07:46:48', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '072c115b-13a8-436b-b0b9-2a1a04dbf8ac'	System	18 Feb 2021 13:46:54
User entered '18 Feb 2021 07:46:48'	System	18 Feb 2021 13:46:54

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-02-25T07:22:55-06:00', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'c1d2e400-076c-4311-84ed-d10e6d3a6f80'	System	25 Feb 2021 13:23:07
User entered 'No (N)'	System	25 Feb 2021 13:23:07

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-02-25T07:22:58-06:00', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'c1d2e400-076c-4311-84ed-d10e6d3a6f80'	System	25 Feb 2021 13:23:07
User entered 'No (N)'	System	25 Feb 2021 13:23:07

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-02-25T07:23:01-06:00', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'c1d2e400-076c-4311-84ed-d10e6d3a6f80'	System	25 Feb 2021 13:23:07
User entered '25 Feb 2021 07:23:01'	System	25 Feb 2021 13:23:07

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-03-04T17:18:51-06:00', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'a1a9c1a5-2ccc-4861-a05e-7587712c4c08'	System	04 Mar 2021 23:23:54
User entered 'No (N)'	System	04 Mar 2021 23:23:54

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-03-04T17:18:54-06:00', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'a1a9c1a5-2ccc-4861-a05e-7587712c4c08'	System	04 Mar 2021 23:23:54
User entered 'No (N)'	System	04 Mar 2021 23:23:54

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-03-04T17:18:57-06:00', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'a1a9c1a5-2ccc-4861-a05e-7587712c4c08'	System	04 Mar 2021 23:23:54
User entered '04 Mar 2021 17:18:57'	System	04 Mar 2021 23:23:54

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 08:37:23

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-03-11T07:11:29-06:00', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'a9389470-10f3-41e1-9c11-af35b3a52c35'	System	11 Mar 2021 13:11:42
User entered 'No (N)'	System	11 Mar 2021 13:11:42

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-03-11T07:11:34-06:00', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'a9389470-10f3-41e1-9c11-af35b3a52c35'	System	11 Mar 2021 13:11:42
User entered 'No (N)'	System	11 Mar 2021 13:11:42

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-03-11T07:11:38-06:00', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'a9389470-10f3-41e1-9c11-af35b3a52c35'	System	11 Mar 2021 13:11:42
User entered '11 Mar 2021 07:11:38'	System	11 Mar 2021 13:11:42

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-03-18T03:10:40-05:00', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '3d7d92eb-5c77-43c0-8ec0-796d04fbfae9'	System	18 Mar 2021 08:10:50
User entered 'No (N)'	System	18 Mar 2021 08:10:50

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-03-18T03:10:45-05:00', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '3d7d92eb-5c77-43c0-8ec0-796d04fbfae9'	System	18 Mar 2021 08:10:50
User entered 'No (N)'	System	18 Mar 2021 08:10:50

FDA-CBER-2022-1614-3509480

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-03-18T03:10:47-05:00', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '3d7d92eb-5c77-43c0-8ec0-796d04fbfae9'	System	18 Mar 2021 08:10:50
User entered '18 Mar 2021 03:10:47'	System	18 Mar 2021 08:10:50

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-03-25T06:45:31-05:00', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '8f2fbc37-4ae3-4716-8c07-20cadf55a303'	System	25 Mar 2021 11:45:44
User entered 'No (N)'	System	25 Mar 2021 11:45:44

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-03-25T06:45:36-05:00', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '8f2fbc37-4ae3-4716-8c07-20cadf55a303'	System	25 Mar 2021 11:45:44
User entered 'No (N)'	System	25 Mar 2021 11:45:44

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-03-25T06:45:38-05:00', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '8f2fbc37-4ae3-4716-8c07-20cadf55a303'	System	25 Mar 2021 11:45:44
User entered '25 Mar 2021 06:45:38'	System	25 Mar 2021 11:45:44

FDA-CBER-2022-1614-3509487

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-04-01T20:26:02-05:00', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'a6a6f49e-739d-4591-a747-09a666068fc2'	System	02 Apr 2021 01:27:37
User entered 'No (N)'	System	02 Apr 2021 01:27:37

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-04-01T20:26:05-05:00', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'a6a6f49e-739d-4591-a747-09a666068fc2'	System	02 Apr 2021 01:27:37
User entered 'No (N)'	System	02 Apr 2021 01:27:37

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-04-01T20:26:09-05:00', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: 'a6a6f49e-739d-4591-a747-09a666068fc2'	System	02 Apr 2021 01:27:37
User entered '01 Apr 2021 20:26:09'	System	02 Apr 2021 01:27:37

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-04-17T16:51:37+02:00', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '07a9cfc8-6e2d-4fbf-a30a-142fe9fd0b26'	System	17 Apr 2021 14:51:47
User entered 'No (N)'	System	17 Apr 2021 14:51:47

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-04-17T16:51:41+02:00', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '07a9cfc8-6e2d-4fbf-a30a-142fe9fd0b26'	System	17 Apr 2021 14:51:47
User entered 'No (N)'	System	17 Apr 2021 14:51:47

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-04-17T16:51:44+02:00', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '07a9cfc8-6e2d-4fbf-a30a-142fe9fd0b26'	System	17 Apr 2021 14:51:47
User entered '17 Apr 2021 16:51:44'	System	17 Apr 2021 14:51:47

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 08:37:23

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-04-22T01:18:04+02:00', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '6c5a258b-dcd5-4446-b69c-f3ac7aa6444c'	System	21 Apr 2021 23:18:18
User entered 'No (N)'	System	21 Apr 2021 23:18:18

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-04-22T01:18:09+02:00', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '6c5a258b-dcd5-4446-b69c-f3ac7aa6444c'	System	21 Apr 2021 23:18:18
User entered 'No (N)'	System	21 Apr 2021 23:18:18

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-04-22T01:18:14+02:00', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '6c5a258b-dcd5-4446-b69c-f3ac7aa6444c'	System	21 Apr 2021 23:18:18
User entered '22 Apr 2021 01:18:14'	System	21 Apr 2021 23:18:18

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-04-29T08:08:39-05:00', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '5f468846-89c6-4458-b992-6c112a5d0cc8'	System	29 Apr 2021 13:10:45
User entered 'No (N)'	System	29 Apr 2021 13:10:45

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-04-29T08:08:42-05:00', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '5f468846-89c6-4458-b992-6c112a5d0cc8'	System	29 Apr 2021 13:10:45
User entered 'No (N)'	System	29 Apr 2021 13:10:45

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-04-29T08:08:44-05:00', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '5f468846-89c6-4458-b992-6c112a5d0cc8'	System	29 Apr 2021 13:10:45
User entered '29 Apr 2021 08:08:44'	System	29 Apr 2021 13:10:45

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 08:37:23

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US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 08:37:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 08:37:23

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Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 08:37:23

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 08:37:23

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 08:37:23

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 08:37:23

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 08:37:23

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US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 08:37:23

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 08:37:23

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 08:37:23

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US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 08:37:23

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 08:37:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 08:37:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 08:37:23

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US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 08:37:23

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 08:37:23

FDA-CBER-2022-1614-3509574

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 08:37:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 08:37:23

FDA-CBER-2022-1614-3509586

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 08:37:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 08:37:23

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 08:37:23

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US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 08:37:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 08:37:23

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 08:37:23

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 08:37:23

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US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 08:37:23

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 08:37:23

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 08:37:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 08:37:23

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US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 08:37:23

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 08:37:23

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 08:37:23

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 08:37:23

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 08:37:23

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 08:37:23

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 08:37:23

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 08:37:23

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US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 08:37:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 08:37:23

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US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 08:37:23

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 08:37:23

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US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 08:37:23

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 08:37:23

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 08:37:23

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US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 08:37:23

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 08:37:23

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US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 08:37:23

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 08:37:23

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 08:37:23

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 08:37:23

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 08:37:23

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 08:37:23

FDA-CBER-2022-1614-3509711

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 08:37:23

FDA-CBER-2022-1614-3509712

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 08:37:23

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 08:37:23

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 08:37:23

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 08:37:23

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US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 08:37:23

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 08:37:23

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 08:37:23

US3912163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:19:18
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '17 Nov 2022 00:01'	System	20 Nov 2020 08:37:23

US3912163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:19:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:37:23
Amendment Manager: User entered '21 Nov 2022 23:59'	System	20 Nov 2020 08:37:23

US3912163

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:19:18

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:07:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-02-27T17:46:01-06:00', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '90877805-9f08-490d-be74-01bf6ab9acd3'	System	27 Feb 2021 23:46:12
User entered 'No (N)'	System	27 Feb 2021 23:46:12

FDA-CBER-2022-1614-3509760

US3912163

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:19:18

Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:07:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76605b52ee18e10a)', Time: '2021-02-27T17:46:09-06:00', User OID: 'PatientReportedOutcome (US3912163)', ODM File OID: '90877805-9f08-490d-be74-01bf6ab9acd3'	System	27 Feb 2021 23:46:12
User entered '27 Feb 2021 17:46:09'	System	27 Feb 2021 23:46:12

US3912163
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:19:18

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	14 Dec 2020 18:51:35

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '9 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	14 Dec 2020 18:51:35

US3912163

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:18

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Contact Made (CONTACT MADE)'	Sandra Clancy (b) (4) (b) (4)	14 Dec 2020 18:51:35

US3912163

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:18

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered empty.	Sandra Clancy (b) (4) (b) (4)	14 Dec 2020 18:51:35

US3912163

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:18

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	14 Dec 2020 18:51:40

FDA-CBER-2022-1614-3509766

US3912163

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:18

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:51:12
User entered '1'	System	14 Dec 2020 18:51:40

US3912163
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:19:18

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:05:41
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	15 Jan 2021 20:56:23

US3912163

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:18

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:05:41
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '14 Jan 2021'	Mia Rountree (b) (4) (b) (4)	15 Jan 2021 20:56:23

US3912163

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:18

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:05:41
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Contact Made (CONTACT MADE)'	Mia Rountree (b) (4) (b) (4)	15 Jan 2021 20:56:23

US3912163
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:19:18
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:05:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
	(b) (4)	
User entered empty.	Mia Rountree (b) (4)	15 Jan 2021 20:56:23
	(b) (4)	

US3912163

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:18

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:05:41
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	15 Jan 2021 20:56:27

US3912163
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:19:18
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:05:41
User entered '1'	System	15 Jan 2021 20:56:27

US3912163
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:19:18

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:05:41
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:52:06

US3912163
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:19:18

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:05:41
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4), (b) (6)	11 Mar 2021 10:10:49
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'confirmed D149 call was less than 117 days after Visit 2' (Site from System).	Sandra Clancy (b) (4) (b) (4)	10 Mar 2021 20:06:55
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	09 Mar 2021 15:52:06
User entered '5 Feb 2021'	(b) (4), (b) (6)	09 Mar 2021 15:52:06

US3912163
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:19:18
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:05:41
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Mar 2021 15:52:06

US3912163

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:18

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:05:41
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:52:06

US3912163

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:18

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:05:41
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 15:52:59

US3912163
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:19:18
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:05:41
User entered '1'	System	09 Mar 2021 15:52:59

US3912163
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:19:18

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:05:41
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	18 Mar 2021 18:27:08
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	17 Mar 2021 20:04:49

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:05:41
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	18 Mar 2021 18:27:08
User entered '15 Mar 2021'	Sandra Clancy (b) (4) (b) (4)	17 Mar 2021 20:04:49

US3912163

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:18

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:05:41
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	18 Mar 2021 18:27:08
User entered 'Contact Made (CONTACT MADE)'	Sandra Clancy (b) (4) (b) (4)	17 Mar 2021 20:04:49

US3912163
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:19:18
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:05:41
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	18 Mar 2021 18:27:08
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Mar 2021 20:04:49

US3912163

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:18

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:05:41
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	18 Mar 2021 18:27:08
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	17 Mar 2021 20:04:53

US3912163
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:19:18
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:05:41
User entered '1'	System	17 Mar 2021 20:04:53

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: COVID-19 Contact
Generated On: 10 Jun 2021 10:19:18
Date of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:46
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:06:39
User entered '9 Dec 2020' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:08:23
User entered '4 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	14 Dec 2020 18:52:23

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: COVID-19 Contact
Generated On: 10 Jun 2021 10:19:18

Time of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:39:41
User closed query 'Time of safety call in Progress Note was 10:00am. Please correct, or clarify. Thank you!' (Site from CRA).	(b) (4), (b) (6)	13 Jan 2021 20:39:38
Query 'Time of safety call in Progress Note was 10:00am. Please correct, or clarify. Thank you!' answered with 'corrected' (Site from CRA).	Sandra Clancy (b) (4)	11 Jan 2021 23:53:49
DataPoint Un-verified.	Sandra Clancy (b) (4)	11 Jan 2021 23:53:41
User entered '10:00' reason for change: Data Entry Error	Sandra Clancy (b) (4)	11 Jan 2021 23:53:41
User opened query 'Time of safety call in Progress Note was 10:00am. Please correct, or clarify. Thank you!' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 17:07:37
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:06:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Dec 2020 05:58:05
Query 'Data is required. Please complete.' answered with 'time is unknown' (Site from System).	Sandra Clancy (b) (4)	14 Dec 2020 18:53:27
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Dec 2020 18:52:23
User entered empty.	Sandra Clancy (b) (4)	14 Dec 2020 18:52:23

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: COVID-19 Contact
Generated On: 10 Jun 2021 10:19:18
Date and Time of Contact (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:46
User entered '9 Dec 2020 10:00'	System	11 Jan 2021 23:53:41
User entered empty.	System	14 Dec 2020 18:52:23

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:19:18

Type of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:46
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:06:39
User entered 'Safety Call (Safety Call)'	Sandra Clancy (b) (4) (b) (4)	14 Dec 2020 18:52:23

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: COVID-19 Contact
Generated On: 10 Jun 2021 10:19:18
Has the subject reported symptoms of SARS-COV-2?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:46
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:06:39
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	14 Dec 2020 18:52:23

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:19:18

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User closed query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 09 Dec 2020 symptom log on log line 1. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 07:31:21
Query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 09 Dec 2020 symptom log on log line 1. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' answered with 'symptom log for 09dec2020 is completed - not sure what you are querying. please place your query on the CRF that is in question. thank you' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	20 Apr 2021 14:15:08
User opened query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 09 Dec 2020 symptom log on log line 1. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 10:51:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
User entered 'Day 1 (Day 1)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09
User entered 'Day 1 (Day 1)'	Sandra Clancy (b) (4) (b) (4)	14 Dec 2020 18:57:12

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:49
User entered '04 Dec 2020' reason for change: Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered '10 Dec 2020' reason for change: Data Entry Error	Sandra Clancy (b) (4)	15 Dec 2020 17:50:34
User entered '4 Dec 2020'	Sandra Clancy (b) (4)	14 Dec 2020 18:57:12

FDA-CBER-2022-1614-3509792

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 10:19:18
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:49
User entered '0' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:26:50
User entered '1' reason for change: Data Entry Error	(b) (4) Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered '0'	(b) (4) Sandra Clancy (b) (4)	14 Dec 2020 18:57:12
	(b) (4)	

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:26:50
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered '95' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:50:34
User entered missing code ND - Not Done.	Sandra Clancy (b) (4) (b) (4)	14 Dec 2020 18:57:12

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US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:19:18

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User entered '%'	System	05 Jan 2021 20:26:50
User entered empty.	System	21 Dec 2020 15:48:23
User entered '%'	System	14 Dec 2020 18:57:12

Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 10:19:18

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:26:50
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered '99.0' F reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:50:34
User entered missing code ND - Not Done.	Sandra Clancy (b) (4) (b) (4)	14 Dec 2020 18:57:12

FDA-CBER-2022-1614-3509796

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:29:07
User signature succeeded.	(b) (4), (b) (6)	20 Apr 2021 18:51:45
User closed query 'Please complete this field. Thank you!' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 15:46:37
Query 'Please complete this field. Thank you!' answered with 'completed' (Site from CRA).	Sandra Clancy (b) (4) (b) (4)	20 Apr 2021 15:19:09
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	20 Apr 2021 15:18:50
Signature has been broken.	Sandra Clancy (b) (4) (b) (4)	20 Apr 2021 15:18:50
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	20 Apr 2021 15:18:50
User opened query 'Please complete this field. Thank you!' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 14:27:51
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:49
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:50:34
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	14 Dec 2020 18:57:12

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US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:19:18

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:49
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:26:50
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'Mild (Mild)'	Sandra Clancy (b) (4) (b) (4)	14 Dec 2020 18:57:12

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:49
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:26:50
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	14 Dec 2020 18:57:12

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:49
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:26:50
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	14 Dec 2020 18:57:12

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US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 10:19:18
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:49
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:26:50
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	15 Dec 2020 17:50:34
User entered 'None (None)'	Sandra Clancy (b) (4)	14 Dec 2020 18:57:12

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Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:19:18

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:49
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:26:50
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	14 Dec 2020 18:57:12

Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 10:19:18
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:49
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:26:50
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:50:34
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	14 Dec 2020 18:57:12

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 10:19:18
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:49
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:26:50
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	14 Dec 2020 18:57:12

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:19:18

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:49
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:26:50
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	14 Dec 2020 18:57:12

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:49
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:26:50
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	14 Dec 2020 18:57:12

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:19:18

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:49
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:26:50
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'Mild (Mild)'	Sandra Clancy (b) (4) (b) (4)	14 Dec 2020 18:57:12

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 10:19:18
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:49
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:26:50
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:51:06
User entered 'Mild (Mild)'	Sandra Clancy (b) (4) (b) (4)	14 Dec 2020 18:57:12

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 10:19:18
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:49
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:26:50
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	14 Dec 2020 18:57:12

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 10:19:18
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:49
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:26:50
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	14 Dec 2020 18:57:12

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:19:18

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:49
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:26:50
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	14 Dec 2020 18:57:12

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Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:19:18

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:49
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:26:50
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	14 Dec 2020 18:57:12

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Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:18

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09
User entered 'Day 2 (Day 2)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:52:42

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 10:19:18
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:50
User entered '05 Dec 2020' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered '11 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:52:42

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Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:18

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:50
User entered '0' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:28:39
User entered '1' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered '0'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:52:42

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:18

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:50
User entered missing code ND - Not Done; reason for change Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:28:39
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered '97'	Sandra Clancy (b) (4)	15 Dec 2020 17:52:42

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:18

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User entered '%'	System	05 Jan 2021 20:28:39
User entered empty.	System	21 Dec 2020 15:48:23
User entered '%'	System	15 Dec 2020 17:52:42

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:18

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:50
User entered missing code ND - Not Done; reason for change Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:28:39
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered '98.4' F	Sandra Clancy (b) (4)	15 Dec 2020 17:52:42

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:18

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:50
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:28:39
	(b) (4)	
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
	(b) (4)	
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:52:42
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 10:19:18
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:50
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:28:39
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:52:42

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:18

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:50
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:28:39
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:52:42

Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 10:19:18
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:50
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:28:39
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:52:42

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 10:19:18
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:50
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:28:39
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:52:42

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Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:18

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:50
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:28:39
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:52:42

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Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:18

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:50
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:28:39
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:52:42

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Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:18

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:50
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:28:39
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:52:42

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Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:18

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:50
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:28:39
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:52:42

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:50
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:28:39
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:52:42

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Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:18

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:50
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:28:39
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'Mild (Mild)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:52:42

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Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:18

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:50
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:28:39
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:52:42

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Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:18

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:50
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:28:39
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:52:42

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Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:18

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:50
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:28:39
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:52:42

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 10:19:18
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:50
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:28:39
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:52:42

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:19:18

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:50
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:28:39
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:52:42

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Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:19:18

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09
User entered 'Day 3 (Day 3)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:53:59

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Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:19:18

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:53
User entered '06 Dec 2020' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered '12 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:53:59

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Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:19:18

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:53
User entered '0' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:30:11
User entered '1' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered '0'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:53:59

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Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:19:18

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:30:11
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered '97'	Sandra Clancy (b) (4)	15 Dec 2020 17:53:59

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:19:18

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User entered '%'	System	05 Jan 2021 20:30:11
User entered empty.	System	21 Dec 2020 15:48:23
User entered '%'	System	15 Dec 2020 17:53:59

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:30:11
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered '97.8' F	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:53:59

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 10:19:18
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:53
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:30:11
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:53:59

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 10:19:18
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:53
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:30:11
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:53:59

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Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:19:18

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:53
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:30:11
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:53:59

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Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:53
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:30:11
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:53:59

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Form: Symptom Log (3)
Generated On: 10 Jun 2021 10:19:18
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:53
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:30:11
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'Severe (Severe)'	Sandra Clancy (b) (4)	15 Dec 2020 17:53:59

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Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:19:18

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:53
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:30:11
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:53:59

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Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:19:18

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:53
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:30:11
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:53:59

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:53
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:30:11
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:53:59

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Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:19:18

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:53
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:30:11
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:53:59

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Form: Symptom Log (3)

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New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:53
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:30:11
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:53:59

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:53
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:30:11
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'Mild (Mild)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:53:59

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Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:19:18

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:53
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:30:11
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:53:59

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Form: Symptom Log (3)
Generated On: 10 Jun 2021 10:19:18
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:53
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:30:11
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:53:59

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Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:53
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:30:11
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:53:59

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Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:19:18

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:53
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:30:11
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:53:59

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 10:19:18
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:53
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:30:11
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:53:59

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Form: Symptom Log (4)

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Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'Day 10 (Day 10)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09
User entered 'Day 4 (Day 4)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:55:09

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Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:18

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:55
User entered '07 Dec 2020' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered '13 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:55:09

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 10:19:18
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:55
User entered '0' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:32:02
User entered '1' reason for change: Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered '0'	Sandra Clancy (b) (4)	15 Dec 2020 17:55:09

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Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:18

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:32:02
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered '98'	Sandra Clancy (b) (4)	15 Dec 2020 17:55:09

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Form: Symptom Log (4)
Generated On: 10 Jun 2021 10:19:18
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User entered '%'	System	05 Jan 2021 20:32:02
User entered empty.	System	21 Dec 2020 15:48:23
User entered '%'	System	15 Dec 2020 17:55:09

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Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:18

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:32:02
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered '98.4' F	Sandra Clancy (b) (4)	15 Dec 2020 17:55:09

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Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:18

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:55
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:32:02
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:55:09

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Generated On: 10 Jun 2021 10:19:18

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:55
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:32:02
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:55:09

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Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:55
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:32:02
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:55:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:18

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:55
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:32:02
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:55:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 10:19:18
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:55
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:32:02
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'Severe (Severe)'	Sandra Clancy (b) (4)	15 Dec 2020 17:55:09

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:18

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:55
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:32:02
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:55:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:18

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:55
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:32:02
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:55:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:18

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:55
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:32:02
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:55:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:18

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:55
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:32:02
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:55:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:18

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:55
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:32:02
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:55:09

FDA-CBER-2022-1614-3509872

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:18

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:55
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:32:02
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'Mild (Mild)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:55:09

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Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:18

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:55
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:32:02
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:55:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:18

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:55
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:32:02
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:55:09

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Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:19:18

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:55
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:32:02
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:55:09

Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 10:19:18
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:55
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:32:02
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'Mild (Mild)'	Sandra Clancy (b) (4)	15 Dec 2020 17:55:09

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 10:19:18
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:55
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:32:02
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:55:09

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Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:19:18

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User closed query 'Please add data from Telemedicine Visits 14-16Dec2020. ' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 21:43:11
User closed query 'Please add data from symptom onset to EDC. ' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 21:43:08
Query 'Please add data from Telemedicine Visits 14-16Dec2020. ' answered with 'will complete as noted' (Site from CRA).	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:04:33
Query 'Please add data from symptom onset to EDC. ' answered with 'will do' (Site from CRA).	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:04:21
User entered 'Day 11 (Day 11)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09
User opened query 'Please add data from Telemedicine Visits 14-16Dec2020. ' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 14:07:08
User opened query 'Please add data from symptom onset to EDC. ' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 14:06:46
User entered 'Day 5 (Day 5)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:56:15

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:19:18

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:56
User entered '08 Dec 2020' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered '14 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:56:15

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 10:19:18
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:56
User entered '0' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:36:03
User entered '1' reason for change: Data Entry Error	(b) (4) Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered '0'	(b) (4) Sandra Clancy (b) (4)	15 Dec 2020 17:56:15
	(b) (4)	

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:36:03
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered '97'	Sandra Clancy (b) (4)	15 Dec 2020 17:56:15

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Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:19:18

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User entered '%'	System	05 Jan 2021 20:36:03
User entered empty.	System	21 Dec 2020 15:48:23
User entered '%'	System	15 Dec 2020 17:56:15

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 10:19:18
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:36:03
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered '98.4' F	Sandra Clancy (b) (4)	15 Dec 2020 17:56:15

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 10:19:18
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:56
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:36:03
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:56:15

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Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:19:18

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:56
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:36:03
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:56:15

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:19:18

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:56
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:36:03
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:56:15

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Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:56
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:36:03
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:56:15

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 10:19:18
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:56
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:36:03
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:56:15

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US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 10:19:18

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:56
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:36:03
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:56:15

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:19:18

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:56
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:36:03
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:56:15

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:19:18

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:56
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:36:03
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:56:15

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:19:18

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:56
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:36:03
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:56:15

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:56
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:36:03
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:56:15

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:19:18

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:56
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:36:03
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'Mild (Mild)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:56:15

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Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:19:18

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:56
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:36:03
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:56:15

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:56
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:36:03
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:56:15

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:19:18

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:56
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:36:03
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:56:15

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:19:18

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:56
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:36:03
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:56:15

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Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:19:18

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:56
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:36:03
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4)	15 Dec 2020 17:56:15

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Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:18

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'Day 1 (Day 1)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:03:31
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:18

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:59
User entered '09 Dec 2020' reason for change: Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 21:03:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Dec 2020 21:03:31
User entered '4 Dec 2020' reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Dec 2020 21:03:31
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 20:56:09
User entered empty.	Sandra Clancy (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 10:19:18
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:59
User entered '0' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:37:58
User entered '1' reason for change: Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered '0'	Sandra Clancy (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:18

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:37:58
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:03:31
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:18

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User entered '%'	System	05 Jan 2021 20:37:58
User entered empty.	System	21 Dec 2020 15:48:23
User entered '%'	System	17 Dec 2020 21:03:31
User entered empty.	System	17 Dec 2020 20:56:09

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Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:18

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:37:58
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:03:31
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:59
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:37:58
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:03:31
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:18

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:37:58
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:03:31
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:18

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:59
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:37:58
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:03:31
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:18

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:59
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:37:58
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:03:31
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 10:19:18
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:59
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:37:58
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:03:31
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:18

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:59
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:37:58
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:03:31
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 10:19:18

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:59
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:37:58
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:03:31
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 10:19:18
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:59
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:37:58
User entered empty; reason for change Data Entry Error	(b) (4) Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Sandra Clancy (b) (4)	17 Dec 2020 21:03:31
User entered empty.	(b) (4) Sandra Clancy (b) (4)	17 Dec 2020 20:56:09
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 10:19:18
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:59
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:37:58
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:03:31
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:18

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:59
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:37:58
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Dec 2020 21:03:31
User entered empty.	Sandra Clancy (b) (4)	17 Dec 2020 20:56:09

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Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:18

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:37:58
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:03:31
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:18

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:37:58
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:03:31
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:18

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:37:58
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:03:31
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:19:18

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:59
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:37:58
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:03:31
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 10:19:18
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:59
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:37:58
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:03:31
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 10:19:18
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:08:59
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:37:58
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Dec 2020 21:03:31
User entered empty.	Sandra Clancy (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 10:19:18
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:06:32
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:18

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:09:27
User entered '10 Dec 2020' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 21:06:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Dec 2020 21:06:32
User entered '5 Dec 2020' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:06:32
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 20:56:09
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 10:19:18
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:09:29
User entered '0'	Sandra Clancy (b) (4)	17 Dec 2020 20:56:09
	(b) (4)	

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Form: Symptom Log (7)
Generated On: 10 Jun 2021 10:19:18
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:09:26
User entered '95' reason for change: Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Sandra Clancy (b) (4)	17 Dec 2020 21:06:32
User entered empty.	Sandra Clancy (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:18

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User entered '%'	System	17 Dec 2020 21:06:32
User entered empty.	System	17 Dec 2020 20:56:09

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:18

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:09:23
User entered '37.2' C reason for change: Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Sandra Clancy (b) (4)	17 Dec 2020 21:06:32
User entered empty.	Sandra Clancy (b) (4)	17 Dec 2020 20:56:09

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:18

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:09:31
User entered 'Mild (Mild)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:06:32
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:18

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:09:33
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:06:32
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:18

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:09:35
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:06:32
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 10:19:18
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:09:36
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Dec 2020 21:06:32
User entered empty.	Sandra Clancy (b) (4)	17 Dec 2020 20:56:09

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Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:18

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:09:39
User entered 'Mild (Mild)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:06:32
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:18

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:09:41
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:06:32
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:18

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:09:44
User entered 'Mild (Mild)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:06:32
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:18

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:09:52
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:06:32
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:18

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:09:54
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:06:32
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:18

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:09:55
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:06:32
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Form: Symptom Log (7)
Generated On: 10 Jun 2021 10:19:18

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:10:00
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:06:32
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:10:06
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Dec 2020 21:06:32
User entered empty.	Sandra Clancy (b) (4)	17 Dec 2020 20:56:09

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Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:18

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:10:08
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:06:32
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:18

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:10:09
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:06:32
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:19:18

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:10:10
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:06:32
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 10:19:18
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:10:12
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:06:32
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:19:18

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:08:02
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 10:19:18
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered '11 Dec 2020' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 21:08:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Dec 2020 21:08:02
User entered '6 Dec 2020' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:08:02
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 20:56:09
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:19:18

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered '0'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:19:18

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:11:17
User entered '97' reason for change: Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Sandra Clancy (b) (4)	17 Dec 2020 21:08:02
User entered empty.	Sandra Clancy (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:19:18

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User entered '%'	System	17 Dec 2020 21:08:02
User entered empty.	System	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 10:19:18
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:11:15
User entered '36.9' C reason for change: Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Sandra Clancy (b) (4)	17 Dec 2020 21:08:02
User entered empty.	Sandra Clancy (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 10:19:18
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:08:02
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Dec 2020 21:08:02
User entered empty.	Sandra Clancy (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:19:18

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:08:02
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 10:19:18
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:08:02
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 10:19:18
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:08:02
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 10:19:18
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Dec 2020 21:08:02
User entered empty.	Sandra Clancy (b) (4)	17 Dec 2020 20:56:09

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Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:19:18

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:08:02
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 10:19:18
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:08:02
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:19:18

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:08:02
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 10:19:18
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:08:02
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 10:19:18

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:11:07
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:08:02
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 10:19:18

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Dec 2020 21:08:02
User entered empty.	Sandra Clancy (b) (4)	17 Dec 2020 20:56:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 10:19:18
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:08:02
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 10:19:18
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:08:02
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 10:19:18
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:08:02
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 10:19:18
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:08:02
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:09:24
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 10:19:18
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered '12 Dec 2020' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 21:09:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Dec 2020 21:09:24
User entered '7 Dec 2020' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:09:24
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 20:56:09
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:19:18

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered '0'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 10:19:18
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:11:25
User entered '97' reason for change: Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Sandra Clancy (b) (4)	17 Dec 2020 21:09:24
User entered empty.	Sandra Clancy (b) (4)	17 Dec 2020 20:56:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 10:19:18
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User entered '%'	System	17 Dec 2020 21:09:24
User entered empty.	System	17 Dec 2020 20:56:09

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:19:18

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:11:26
User entered '36.6' C reason for change: Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Sandra Clancy (b) (4)	17 Dec 2020 21:09:24
User entered empty.	Sandra Clancy (b) (4)	17 Dec 2020 20:56:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 10:19:18
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:09:24
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 10:19:18
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:09:24
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:19:18

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:09:24
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 10:19:18
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:09:24
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 10:19:18
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:11:35
User entered 'Severe (Severe)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:09:24
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 10:19:18

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:09:24
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:09:24
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:19:18

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:09:24
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:19:18

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:09:24
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:19:18

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:09:24
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:19:18

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:11:37
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Dec 2020 21:09:24
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	17 Dec 2020 20:56:09
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:19:18

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:11:39
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:09:24
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 10:19:18
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:09:24
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:19:18

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:09:24
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:19:18

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:11:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:09:24
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:19:18

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:09:24
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 10:19:18
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
User entered 'Day 10 (Day 10)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:10:47
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 10:19:18
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered '13 Dec 2020' reason for change: Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 21:10:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Dec 2020 21:10:47
User entered '8 Dec 2020' reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Dec 2020 21:10:47
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 20:56:09
User entered empty.	Sandra Clancy (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 10:19:18
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered '0'	Sandra Clancy (b) (4)	17 Dec 2020 20:56:09
	(b) (4)	

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 10:19:18
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:11:50
User entered '98' reason for change: Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Sandra Clancy (b) (4)	17 Dec 2020 21:10:47
User entered empty.	Sandra Clancy (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 10:19:18
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User entered '%'	System	17 Dec 2020 21:10:47
User entered empty.	System	17 Dec 2020 20:56:09

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:11:52
User entered '36.9' C reason for change: Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Sandra Clancy (b) (4)	17 Dec 2020 21:10:47
User entered empty.	Sandra Clancy (b) (4)	17 Dec 2020 20:56:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 10:19:18
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:10:47
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 10:19:18

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:10:47
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 10:19:18
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:10:47
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:19:18

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:10:47
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 10:19:18
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:11:58
User entered 'Severe (Severe)' reason for change: Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Dec 2020 21:10:47
User entered empty.	Sandra Clancy (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:19:18

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:10:47
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:19:18

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:10:47
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 10:19:18
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:10:47
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:19:18

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:10:47
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:19:18

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:10:47
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:12:04
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:10:47
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

FDA-CBER-2022-1614-3510005

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:19:18

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:12:06
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:10:47
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:19:18

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:10:47
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 10:19:18

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:10:47
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 10:19:18
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:12:09
User entered 'Mild (Mild)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:10:47
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:19:18

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:10:47
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 20:56:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:18

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
User entered 'Day 11 (Day 11)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'Day 6 (Day 6)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:12:38

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:18

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered '14 Dec 2020' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered '9 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:12:38

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:18

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered '0'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:12:38

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:18

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:12:18
User entered '97' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered missing code ND - Not Done.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:12:38

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User entered '%'	System	17 Dec 2020 21:12:38

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:18

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:12:15
User entered '36.9' C reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered missing code ND - Not Done.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:12:38

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:18

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:12:38

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Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:18

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'Mild (Mild)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:12:38

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:18

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:12:38

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 10:19:18
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:12:38

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Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:18

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:12:24
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:12:38

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:18

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:12:38

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Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:18

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:12:38

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:18

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:12:38

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:18

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:12:38

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:18

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:12:38

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Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:18

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:12:30
User entered 'Mild (Mild)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:12:38

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Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:18

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'Mild (Mild)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:12:38

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:18

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:12:38

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:12:38

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Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:12:33
User entered 'Mild (Mild)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:12:38

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:19:18

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:12:38

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Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:18

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
User entered 'Day 12 (Day 12)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:16:57

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Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:18

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered '15 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:16:57

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (12)
Generated On: 10 Jun 2021 10:19:18
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered '0'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:16:57

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Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:18

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:12:40
User entered '97'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:16:57

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (12)
Generated On: 10 Jun 2021 10:19:18
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User entered '%'	System	17 Dec 2020 21:16:57

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Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:18

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:12:42
User entered '36.9' C reason for change: Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:54:55
User entered '36' F reason for change: Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
User entered '98.4' F	Sandra Clancy (b) (4)	17 Dec 2020 21:16:57

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (12)
Generated On: 10 Jun 2021 10:19:18
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:16:57

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Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:18

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:16:57

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:18

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:16:57

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (12)
Generated On: 10 Jun 2021 10:19:18
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:16:57

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (12)
Generated On: 10 Jun 2021 10:19:18
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:12:50
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:56:25
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:16:57

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Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:18

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4)	17 Dec 2020 21:16:57
	(b) (4)	

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Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:18

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:16:57

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Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:18

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:16:57

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:18

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:16:57

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Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:18

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:16:57

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (12)
Generated On: 10 Jun 2021 10:19:18
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:12:54
User entered 'Mild (Mild)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:16:57

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:18

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:16:57

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:18

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:16:57

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:18

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:16:57

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (12)
Generated On: 10 Jun 2021 10:19:18
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:12:56
User entered 'Mild (Mild)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:16:57

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:19:18

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4)	17 Dec 2020 21:16:57

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (13)
Generated On: 10 Jun 2021 10:19:18
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
User entered 'Day 13 (Day 13)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:19:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:18

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered '16 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:19:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:18

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered '0'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:19:09

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Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:18

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:13:02
User entered '98'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:19:09

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (13)
Generated On: 10 Jun 2021 10:19:18
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User entered '%'	System	17 Dec 2020 21:19:09

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Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:18

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:13:04
User entered '36.8' C reason for change: Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:54:55
User entered '98.2' F	(b) (4) Sandra Clancy (b) (4)	17 Dec 2020 21:19:09
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:18

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:19:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:18

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:19:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:18

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4)	17 Dec 2020 21:19:09
	(b) (4)	

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:19:09

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (13)
Generated On: 10 Jun 2021 10:19:18
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:13:07
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:57:04
User entered 'Mild (Mild)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:19:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:18

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:19:09

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Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:18

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:19:09

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (13)
Generated On: 10 Jun 2021 10:19:18
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:19:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:18

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:19:09

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Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:18

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:19:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:18

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:13:12
User entered 'Mild (Mild)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:19:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:18

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:19:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:18

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:19:09

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:19:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:18

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:13:15
User entered 'Moderate (Moderate)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:19:09

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:19:18

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:19:09

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Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:19:18

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
User entered 'Day 14 (Day 14)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:59:15

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Generated On: 10 Jun 2021 10:19:18

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered '17 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:59:15

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Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered '0'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:59:15

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Generated On: 10 Jun 2021 10:19:18

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:13:23
User entered '98'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:59:15

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User entered '%'	System	17 Dec 2020 21:59:15

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Generated On: 10 Jun 2021 10:19:18

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:13:24
User entered '36.2' C reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:54:55
User entered '97.2' F	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:59:15

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:19:18

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:59:15

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Generated On: 10 Jun 2021 10:19:18

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:59:15

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US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (14)
Generated On: 10 Jun 2021 10:19:18
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:59:15

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:19:18

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:59:15

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:13:28
User entered 'Moderate (Moderate)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:59:15

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:19:18

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:59:15

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:19:18

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:59:15

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EAB) (1725)

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Generated On: 10 Jun 2021 10:19:18

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:59:15

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Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:19:18

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:59:15

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:19:18

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:59:15

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:19:18

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:13:31
User entered 'Mild (Mild)'	Sandra Clancy (b) (4)	17 Dec 2020 21:59:15
	(b) (4)	

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Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:19:18

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:59:15

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (14)
Generated On: 10 Jun 2021 10:19:18
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:59:15

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (14)
Generated On: 10 Jun 2021 10:19:18
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:59:15

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Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:19:18

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:40:54
User closed query 'Per Telemedicine Contact dated 17Dec2020, subject reported mild diarrhea. Please remove data, or clarify. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	13 Jan 2021 20:40:49
Query 'Per Telemedicine Contact dated 17Dec2020, subject reported mild diarrhea. Please remove data, or clarify. Thank you! ' answered with 'corrected' (Site from CRA).	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:55:49
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:55:29
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:55:29
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User opened query 'Per Telemedicine Contact dated 17Dec2020, subject reported mild diarrhea. Please remove data, or clarify. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 17:14:53
User entered 'None (None)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:59:15

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:19:18

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:40:56
User closed query 'Per Telemedicine Contact dated 17Dec2020, subject did not report sore throat. Please remove data, or clarify. Thank you!' (Site from CRA).	(b) (4), (b) (6)	13 Jan 2021 20:40:52
Query 'Per Telemedicine Contact dated 17Dec2020, subject did not report sore throat. Please remove data, or clarify. Thank you!' answered with 'corrected' (Site from CRA).	Sandra Clancy (b) (4)	11 Jan 2021 23:55:56
DataPoint Un-verified.	Sandra Clancy (b) (4)	11 Jan 2021 23:55:29
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	11 Jan 2021 23:55:29
User opened query 'Per Telemedicine Contact dated 17Dec2020, subject did not report sore throat. Please remove data, or clarify. Thank you!' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 17:14:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:13:36
User entered 'Mild (Mild)'	Sandra Clancy (b) (4)	17 Dec 2020 21:59:15

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US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (15)
Generated On: 10 Jun 2021 10:19:18
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
User entered 'Day 15 (Day 15)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 15:54:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 15:54:55
User entered '18 Dec 2020' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:54:55
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 15:48:23
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:19:18

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered '0'	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:19:18

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:15:03
User entered '98' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:54:55
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (15)
Generated On: 10 Jun 2021 10:19:18
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User entered '%'	System	21 Dec 2020 15:54:55
User entered empty.	System	21 Dec 2020 15:48:23

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (15)
Generated On: 10 Jun 2021 10:19:18
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:15:05
User entered '36.3' C reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:54:55
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (15)
Generated On: 10 Jun 2021 10:19:18
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (15)
Generated On: 10 Jun 2021 10:19:18
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:19:18

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:19:18

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (15)
Generated On: 10 Jun 2021 10:19:18
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (15)
Generated On: 10 Jun 2021 10:19:18

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:19:18

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (15)
Generated On: 10 Jun 2021 10:19:18
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:19:18

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (15)
Generated On: 10 Jun 2021 10:19:18
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:15:13
User entered 'Mild (Mild)' reason for change: Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4)	21 Dec 2020 15:48:23

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Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:19:18

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:19:18

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:19:18

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Form: Symptom Log (15)
Generated On: 10 Jun 2021 10:19:18
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4)	21 Dec 2020 15:48:23
	(b) (4)	

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Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:19:18

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
User entered 'Day 16 (Day 16)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

FDA-CBER-2022-1614-3510121

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (16)
Generated On: 10 Jun 2021 10:19:18
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 15:57:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 15:57:31
User entered '19 Dec 2020' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:31
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 15:48:23
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:19:18

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered '0'	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (16)
Generated On: 10 Jun 2021 10:19:18
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:15:20
User entered '98' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:19:18

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User entered '%'	System	21 Dec 2020 15:57:31
User entered empty.	System	21 Dec 2020 15:48:23

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:19:18

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:15:22
User entered '36.4' C reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (16)
Generated On: 10 Jun 2021 10:19:18
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (16)
Generated On: 10 Jun 2021 10:19:18
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:19:18

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:19:18

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (16)
Generated On: 10 Jun 2021 10:19:18
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:15:29
User entered 'Mild (Mild)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (16)
Generated On: 10 Jun 2021 10:19:18
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:19:18

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:19:18

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:19:18

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:19:18

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:19:18

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (16)
Generated On: 10 Jun 2021 10:19:18

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4)	21 Dec 2020 15:48:23

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Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:19:18

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:19:18

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:19:18

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:19:18

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:31
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (17)
Generated On: 10 Jun 2021 10:19:18
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
User entered 'Day 17 (Day 17)' reason for change: Data Entry Error	Monique Gawlik (b) (4)	23 Dec 2020 15:46:48
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 21:53:41
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:41
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 15:46:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Dec 2020 15:46:48
User entered '20 Dec 2020' reason for change: Data Entry Error	Monique Gawlik (b) (4)	23 Dec 2020 15:46:48
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 21:53:41
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:41
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 15:48:23
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:19:18

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 21:53:41
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:41
User entered '0'	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (17)
Generated On: 10 Jun 2021 10:19:18
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:15:36
User entered '97' reason for change: Data Entry Error	Monique Gawlik (b) (4)	23 Dec 2020 15:46:48
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 21:53:41
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:41
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:19:18

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User entered '%'	System	23 Dec 2020 15:46:48
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 21:53:41
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:41
User entered empty.	System	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:19:18

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:15:38
User entered '36.4' C reason for change: Data Entry Error	Monique Gawlik (b) (4)	23 Dec 2020 15:46:48
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 21:53:41
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:41
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (17)
Generated On: 10 Jun 2021 10:19:18
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Monique Gawlik (b) (4)	23 Dec 2020 15:46:48
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4)	22 Dec 2020 21:53:41
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4)	21 Dec 2020 15:57:41
User entered empty.	Mia Rountree (b) (4)	21 Dec 2020 15:48:23

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (17)
Generated On: 10 Jun 2021 10:19:18
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Monique Gawlik (b) (4)	23 Dec 2020 15:46:48
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 21:53:41
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:41
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:19:18

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Monique Gawlik (b) (4)	23 Dec 2020 15:46:48
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 21:53:41
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:41
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:19:18

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Monique Gawlik (b) (4)	23 Dec 2020 15:46:48
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 21:53:41
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:41
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (17)
Generated On: 10 Jun 2021 10:19:18
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Monique Gawlik (b) (4)	23 Dec 2020 15:46:48
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 21:53:41
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:41
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

FDA-CBER-2022-1614-3510153

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:19:18

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Monique Gawlik (b) (4)	23 Dec 2020 15:46:48
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 21:53:41
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:41
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

FDA-CBER-2022-1614-3510154

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (17)
Generated On: 10 Jun 2021 10:19:18
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Monique Gawlik (b) (4)	23 Dec 2020 15:46:48
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 21:53:41
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:41
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (17)
Generated On: 10 Jun 2021 10:19:18
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Monique Gawlik (b) (4)	23 Dec 2020 15:46:48
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 21:53:41
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:41
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:19:18

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Monique Gawlik (b) (4)	23 Dec 2020 15:46:48
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 21:53:41
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:41
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

FDA-CBER-2022-1614-3510157

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:19:18

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Monique Gawlik (b) (4)	23 Dec 2020 15:46:48
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 21:53:41
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:41
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:19:18

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:15:44
User entered 'Mild (Mild)' reason for change: Data Entry Error	Monique Gawlik (b) (4)	23 Dec 2020 15:46:48
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 21:53:41
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:41
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:19:18

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Monique Gawlik (b) (4)	23 Dec 2020 15:46:48
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 21:53:41
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:41
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:19:18

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Monique Gawlik (b) (4)	23 Dec 2020 15:46:48
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 21:53:41
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:41
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:19:18

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Monique Gawlik (b) (4)	23 Dec 2020 15:46:48
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 21:53:41
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:41
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:19:18

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Monique Gawlik (b) (4)	23 Dec 2020 15:46:48
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 21:53:41
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:41
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:19:18

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Monique Gawlik (b) (4)	23 Dec 2020 15:46:48
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 21:53:41
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:41
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:19:18

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
User entered 'Day 18 (Day 18)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:41:18
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:38:54
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:45
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:19:18

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 20:41:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Jan 2021 20:41:18
User entered '21 Dec 2020' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:41:18
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:38:54
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:45
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 15:48:23
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:19:18

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:38:54
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:45
User entered '0'	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:19:18

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:15:50
User entered '98' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:41:18
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4)	05 Jan 2021 20:38:54
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4)	21 Dec 2020 15:57:45
User entered empty.	Mia Rountree (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:19:18

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User entered '%'	System	05 Jan 2021 20:41:18
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:38:54
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:45
User entered empty.	System	21 Dec 2020 15:48:23

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (18)
Generated On: 10 Jun 2021 10:19:18
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:15:52
User entered '97.4' F reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:41:18
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:38:54
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:45
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (18)
Generated On: 10 Jun 2021 10:19:18
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:41:18
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:38:54
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:45
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (18)
Generated On: 10 Jun 2021 10:19:18
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:41:18
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:38:54
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:45
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:19:18

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:41:18
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:38:54
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:45
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:19:18

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:41:18
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4)	05 Jan 2021 20:38:54
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4)	21 Dec 2020 15:57:45
User entered empty.	Mia Rountree (b) (4)	21 Dec 2020 15:48:23

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:19:18

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:41:18
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:38:54
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:45
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:41:18
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:38:54
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:45
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:19:18

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:41:18
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:38:54
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:45
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (18)
Generated On: 10 Jun 2021 10:19:18
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:41:18
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:38:54
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:45
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:19:18

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:41:18
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4)	05 Jan 2021 20:38:54
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4)	21 Dec 2020 15:57:45
User entered empty.	Mia Rountree (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:19:18

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:41:18
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:38:54
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:45
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:15:55
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:41:47
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:41:18
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:38:54
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:45
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:19:18

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:41:18
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:38:54
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:45
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:19:18

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:41:18
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4)	05 Jan 2021 20:38:54
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4)	21 Dec 2020 15:57:45
User entered empty.	Mia Rountree (b) (4)	21 Dec 2020 15:48:23

FDA-CBER-2022-1614-3510183

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:19:18

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:41:18
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4)	05 Jan 2021 20:38:54
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4)	21 Dec 2020 15:57:45
User entered empty.	Mia Rountree (b) (4)	21 Dec 2020 15:48:23

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US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:19:18

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:41:47
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:41:18
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:38:54
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:45
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:19:18

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:41:18
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4)	05 Jan 2021 20:38:54
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4)	21 Dec 2020 15:57:45
User entered empty.	Mia Rountree (b) (4)	21 Dec 2020 15:48:23

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:19:18

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
User entered 'Day 19 (Day 19)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:43:35
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:39:04
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:50
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:19:18

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 20:43:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Jan 2021 20:43:35
User entered '22 Dec 2020' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:43:35
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:39:04
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:50
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 15:48:23
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:19:18

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:39:04
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:50
User entered '0'	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:19:18

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:28:46
User entered '98' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:43:35
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:39:04
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:50
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:19:18

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User entered '%'	System	05 Jan 2021 20:43:35
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:39:04
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:50
User entered empty.	System	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (19)
Generated On: 10 Jun 2021 10:19:18
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:28:48
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Jan 2021 20:46:37
User entered '97.4' F reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:46:37
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Jan 2021 20:43:35
User entered '97.4' (non-conformant).	Sandra Clancy (b) (4)	05 Jan 2021 20:43:35
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4)	05 Jan 2021 20:39:04
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4)	21 Dec 2020 15:57:50
User entered empty.	Mia Rountree (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (19)
Generated On: 10 Jun 2021 10:19:18
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:43:35
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:39:04
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:50
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:19:18

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:43:35
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:39:04
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:50
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:19:18

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:43:35
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:39:04
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:50
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (19)
Generated On: 10 Jun 2021 10:19:18
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:43:35
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:39:04
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:50
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (19)
Generated On: 10 Jun 2021 10:19:18

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:28:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:43:35
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4)	05 Jan 2021 20:39:04
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4)	21 Dec 2020 15:57:50
User entered empty.	Mia Rountree (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:19:18

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:43:35
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:39:04
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:50
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:19:18

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:43:35
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:39:04
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:50
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Symptom Log (19)
Generated On: 10 Jun 2021 10:19:18
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:43:35
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:39:04
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:50
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:19:18

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:43:35
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:39:04
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:50
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:19:18

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:43:35
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:39:04
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:50
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:19:18

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:43:35
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:39:04
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:50
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:43:35
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:39:04
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:50
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:19:18

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Jan 2021 20:43:35
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4)	05 Jan 2021 20:39:04
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4)	21 Dec 2020 15:57:50
User entered empty.	Mia Rountree (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:19:18

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:43:35
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:39:04
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:50
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:19:18

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:43:35
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:39:04
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:50
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:19:18

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:42:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:43:35
DataPoint activated with code reason code Data required.	Sandra Clancy (b) (4) (b) (4)	05 Jan 2021 20:39:04
DataPoint inactivated with code reason code Data not required.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:57:50
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:48:23

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:19:18

Date of Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:02
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:59
User entered '10 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:58:51

FDA-CBER-2022-1614-3510209

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:19:18

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:02
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:00
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:58:51

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:19:18

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:02
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:31:02
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	28 Dec 2020 17:37:31
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'completed' (Site from System).	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:14:00
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	15 Dec 2020 17:58:51
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:58:51

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: COVID Diagnostic Test
Generated On: 10 Jun 2021 10:19:18
Date of Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:02
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:31:04
User closed query 'Per Preclarus Lab Portal, Illness D1 Nasal Swab for US3912163 was collected on 10-Dec-2020. Please clarify or correct. Thank you!' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 21:31:48
Query 'Per Preclarus Lab Portal, Illness D1 Nasal Swab for US3912163 was collected on 10-Dec-2020. Please clarify or correct. Thank you!' answered with 'corrected' (Site from CRA).	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:14:41
User entered '10 Dec 2020' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:14:33
User opened query 'Per Preclarus Lab Portal, Illness D1 Nasal Swab for US3912163 was collected on 10-Dec-2020. Please clarify or correct. Thank you!' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 14:10:23
User entered '14 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:58:51

FDA-CBER-2022-1614-3510212

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: COVID Diagnostic Test
Generated On: 10 Jun 2021 10:19:18
Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:02
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:11
User entered 'Nasal Swab (Nasal Swab)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:58:51

FDA-CBER-2022-1614-3510213

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: COVID Diagnostic Test
Generated On: 10 Jun 2021 10:19:18
Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:02
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:15
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:58:51

Was this diagnostic test performed at a lab other than the Study Central Lab?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:02
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:17
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:58:51

FDA-CBER-2022-1614-3510215

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: COVID Diagnostic Test
Generated On: 10 Jun 2021 10:19:18
Lab/ Institution Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:02
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:20
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:58:51

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: COVID Diagnostic Test
Generated On: 10 Jun 2021 10:19:18
CLIA Certified?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:02
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:22
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 17:58:51

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:02
User entered '1'	System	15 Dec 2020 17:58:51

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:19:18

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

FDA-CBER-2022-1614-3510219

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 10:19:18
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered empty.	Sandra Clancy (b) (4)	15 Dec 2020 18:00:09
	(b) (4)	

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 10:19:18
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 10:19:18
Respiratory Rate

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:19:18

Did the subject have Heart Rate ≥ 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 10:19:18
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 10:19:18
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

Heart Rate

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

FDA-CBER-2022-1614-3510226

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:19:18

Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered empty.	Sandra Clancy (b) (4)	15 Dec 2020 18:00:09

FDA-CBER-2022-1614-3510228

US3912163

Folder: Covid-19 Assessment 09 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 10:19:18
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:19:18

Oxygen Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:19:18

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	22 Dec 2020 16:00:08
User closed query 'Please complete eCRF field. ' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 18:53:40
Query 'Please complete eCRF field. ' answered with 'corrected' (Site from CRA).	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:15:12
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:14:52
User opened query 'Please complete eCRF field. ' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 14:14:26
Query 'Data is required. Please complete.' answered with 'data unknown' (Site from System).	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:28
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 18:00:09
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

FDA-CBER-2022-1614-3510231

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 10:19:18
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 10:19:18
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 10:19:18
PaO2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

US3912163

Folder: Covid-19 Assessment 09 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 10:19:18

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
User closed query 'Per CDM: It appears that both 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is 'No', yet data is recorded for 'If Yes to either Did subject require any of the following'. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:33:17
Query 'Per CDM: It appears that both 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is 'No', yet data is recorded for 'If Yes to either Did subject require any of the following'. Please review and update accordingly. ' answered with 'Data corrected ' (Site from DM).	Mia Rountree (b) (4) (b) (4)	26 Feb 2021 19:02:26
User opened query 'Per CDM: It appears that both 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is 'No', yet data is recorded for 'If Yes to either Did subject require any of the following'. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	14 Feb 2021 22:12:55
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

FDA-CBER-2022-1614-3510235

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:19:18

Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

Folder: Covid-19 Assessment 09 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 10:19:18

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 18:00:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Dec 2020 18:00:49
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	15 Dec 2020 18:00:49
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 18:00:09
User entered empty.	Sandra Clancy (b) (4)	15 Dec 2020 18:00:09
	(b) (4)	

FDA-CBER-2022-1614-3510237

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:19:18

Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

High-Flow Oxygen?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
Query 'Please complete eCRF field. ' canceled (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:04:42
User opened query 'Please complete eCRF field. ' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:03:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:01:06
DataPoint Un-verified.	Mia Rountree (b) (4) (b) (4)	26 Feb 2021 19:02:02
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	26 Feb 2021 19:02:02
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User closed query 'Please complete eCRF field. ' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 18:53:44
Query 'Please complete eCRF field. ' answered with 'corrected' (Site from CRA).	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:15:20
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:14:52
User opened query 'Please complete eCRF field. ' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 14:12:56
Query 'Please complete eCRF.' canceled (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 14:12:48
User opened query 'Please complete eCRF.' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 14:12:41
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

FDA-CBER-2022-1614-3510239

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:19:18

Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

US3912163

Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:19:18

End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered empty.	Sandra Clancy (b) (4)	15 Dec 2020 18:00:09
	(b) (4)	

Folder: Covid-19 Assessment 09 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 10:19:18

Non-Invasive Ventilation?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:06:17
Query 'Please complete eCRF field. ' canceled (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:04:44
User opened query 'Please complete eCRF field. ' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:03:42
DataPoint Un-verified.	Mia Rountree (b) (4)	26 Feb 2021 19:02:02
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	26 Feb 2021 19:02:02
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User closed query 'Please complete eCRF field. ' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 18:53:48
Query 'Please complete eCRF field. ' answered with 'corrected' (Site from CRA).	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:15:27
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:14:52
User opened query 'Please complete eCRF field. ' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 14:13:03
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 10:19:18
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 10:19:18
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

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Generated On: 10 Jun 2021 10:19:18

Mechanical Ventilation?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:06:17
Query 'Please complete eCRF field. ' canceled (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:04:46
User opened query 'Please complete eCRF field. ' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:03:40
DataPoint Un-verified.	Mia Rountree (b) (4)	26 Feb 2021 19:02:02
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	26 Feb 2021 19:02:02
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User closed query 'Please complete eCRF field. ' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 18:53:50
Query 'Please complete eCRF field. ' answered with 'corrected' (Site from CRA).	Sandra Clancy (b) (4)	17 Dec 2020 15:15:33
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Dec 2020 15:14:52
User opened query 'Please complete eCRF field. ' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 14:13:10
User entered empty.	Sandra Clancy (b) (4)	15 Dec 2020 18:00:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 10:19:18
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 10:19:18
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 10:19:18
ECMO?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:06:17
Query 'Please complete eCRF field. ' canceled (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:04:47
User opened query 'Please complete eCRF field. ' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:03:30
DataPoint Un-verified.	Mia Rountree (b) (4)	26 Feb 2021 19:02:02
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	26 Feb 2021 19:02:02
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User closed query 'Please complete eCRF field. ' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 18:53:53
Query 'Please complete eCRF field. ' answered with 'corrected' (Site from CRA).	Sandra Clancy (b) (4)	17 Dec 2020 15:15:41
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Dec 2020 15:14:52
User opened query 'Please complete eCRF field. ' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 14:13:16
User entered empty.	Sandra Clancy (b) (4)	15 Dec 2020 18:00:09

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Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:19:18

Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 10:19:18
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

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Generated On: 10 Jun 2021 10:19:18

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:06:17
Query 'Please complete eCRF field. ' canceled (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:04:51
User opened query 'Please complete eCRF field. ' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:03:28
DataPoint Un-verified.	Mia Rountree (b) (4) (b) (4)	26 Feb 2021 19:02:02
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	26 Feb 2021 19:02:02
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User closed query 'Please complete eCRF field. ' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 18:53:55
Query 'Please complete eCRF field. ' answered with 'corrected' (Site from CRA).	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:15:54
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:14:52
User opened query 'Please complete eCRF field. ' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 14:13:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

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Folder: Covid-19 Assessment 09 Dec 2020

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Generated On: 10 Jun 2021 10:19:18

Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

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Folder: Covid-19 Assessment 09 Dec 2020

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Generated On: 10 Jun 2021 10:19:18

End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

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Evidence of Shock Requires
Vasopressors

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:06:17
Query 'Please complete eCRF field. ' canceled (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:04:53
User opened query 'Please complete eCRF field. ' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:03:26
DataPoint Un-verified.	Mia Rountree (b) (4)	26 Feb 2021 19:02:02
User entered empty; reason for change Data Entry Error	(b) (4) Mia Rountree (b) (4)	26 Feb 2021 19:02:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:31:40
User closed query 'Please complete eCRF field. ' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 18:53:57
Query 'Please complete eCRF field. ' answered with 'corrected' (Site from CRA).	Sandra Clancy (b) (4)	17 Dec 2020 15:15:59
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Sandra Clancy (b) (4)	17 Dec 2020 15:14:52
User opened query 'Please complete eCRF field. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	17 Dec 2020 14:13:33
User entered empty.	Sandra Clancy (b) (4)	15 Dec 2020 18:00:09
	(b) (4)	

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Generated On: 10 Jun 2021 10:19:18

Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

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Generated On: 10 Jun 2021 10:19:18

End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

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Generated On: 10 Jun 2021 10:19:18

Acute Renal Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:06:17
Query 'Please complete eCRF field. ' canceled (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:05:33
User opened query 'Please complete eCRF field. ' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:03:22
DataPoint Un-verified.	Mia Rountree (b) (4) (b) (4)	26 Feb 2021 19:02:02
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	26 Feb 2021 19:02:02
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User closed query 'Please complete eCRF field. ' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 18:53:59
Query 'Please complete eCRF field. ' answered with 'corrected' (Site from CRA).	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:16:06
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:14:52
User opened query 'Please complete eCRF field. ' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 14:13:38
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 10:19:18
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

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Generated On: 10 Jun 2021 10:19:18

Hepatic Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:06:17
Query 'Please complete eCRF field. ' canceled (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:05:35
User opened query 'Please complete eCRF field. ' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:03:20
DataPoint Un-verified.	Mia Rountree (b) (4) (b) (4)	26 Feb 2021 19:02:02
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	26 Feb 2021 19:02:02
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User closed query 'Please complete eCRF field. ' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 18:54:01
Query 'Please complete eCRF field. ' answered with 'corrected' (Site from CRA).	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:16:13
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:14:52
User opened query 'Please complete eCRF field. ' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 14:13:51
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

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Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 10:19:18
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

Neurologic Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:06:17
Query 'Please complete eCRF field. ' canceled (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:05:38
User opened query 'Please complete eCRF field. ' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:03:17
DataPoint Un-verified.	Mia Rountree (b) (4) (b) (4)	26 Feb 2021 19:02:02
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	26 Feb 2021 19:02:02
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User closed query 'Please complete eCRF field. ' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 18:55:15
Query 'Please complete eCRF field. ' answered with 'corrected' (Site from CRA).	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:16:20
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:14:52
User opened query 'Please complete eCRF field. ' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 14:13:55
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 10:19:18
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

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Folder: Covid-19 Assessment 09 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 10:19:18
Clinical Evidence

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:06:17
Query 'Please complete eCRF field. ' canceled (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:05:40
User opened query 'Please complete eCRF field. ' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:03:14
DataPoint Un-verified.	Mia Rountree (b) (4)	26 Feb 2021 19:02:02
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	26 Feb 2021 19:02:02
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User closed query 'Please complete eCRF field. ' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 18:55:17
Query 'Please complete eCRF field. ' answered with 'corrected' (Site from CRA).	Sandra Clancy (b) (4)	17 Dec 2020 15:16:28
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Dec 2020 15:14:52
User opened query 'Please complete eCRF field. ' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 14:14:01
User entered empty.	Sandra Clancy (b) (4)	15 Dec 2020 18:00:09

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Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:19:18

Date of Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

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Radiographical Evidence

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:06:17
Query 'Please complete eCRF field. ' canceled (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:05:42
User opened query 'Please complete eCRF field. ' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:03:10
DataPoint Un-verified.	Mia Rountree (b) (4)	26 Feb 2021 19:02:02
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	26 Feb 2021 19:02:02
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User closed query 'Please complete eCRF field. ' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 18:55:19
Query 'Please complete eCRF field. ' answered with 'corrected' (Site from CRA).	Sandra Clancy (b) (4)	17 Dec 2020 15:16:34
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Dec 2020 15:14:52
User opened query 'Please complete eCRF field. ' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 14:14:06
User entered empty.	Sandra Clancy (b) (4)	15 Dec 2020 18:00:09

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Generated On: 10 Jun 2021 10:19:18

Date of Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

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Admission to an intensive care unit due to SARS-CoV-2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:06:17
Query 'Please complete eCRF field. ' canceled (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:03:08
User opened query 'Please complete eCRF field. ' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:03:06
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Feb 2021 19:02:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Feb 2021 19:02:13
User entered 'No (N)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	26 Feb 2021 19:02:13
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Feb 2021 19:02:02
DataPoint Un-verified.	Mia Rountree (b) (4) (b) (4)	26 Feb 2021 19:02:02
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	26 Feb 2021 19:02:02
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 18:01:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Dec 2020 18:01:26
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:01:26
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 18:00:09
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 10:19:18
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 10 Jun 2021 10:19:18
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:07
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:31:40
User entered empty.	Sandra Clancy (b) (4) (b) (4)	15 Dec 2020 18:00:09

US3912163
Folder: Covid-19 Assessment 09 Dec 2020
Form: Generate Next COVID-19 Assessment
Generated On: 10 Jun 2021 10:19:18
Generate Next COVID-19 Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:43:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:50
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	27 Jan 2021 15:06:02

US3912163

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:19:18

Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User accepted default value 'Day 3 (Day 3)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:32:30

US3912163

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:19:18

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	15 Mar 2021 18:51:37
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:35:27
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:32:30

US3912163

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:19:18

Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	15 Mar 2021 18:51:37
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:35:27
User entered '12 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:32:30

US3912163

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:19:18

Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User accepted default value 'Day 5 (Day 5)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:32:43

US3912163

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:19:18

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	15 Mar 2021 18:51:37
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:35:33
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:32:43

US3912163

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:19:18

Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	15 Mar 2021 18:51:37
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:35:33
User entered '14 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:32:43

Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 10 Jun 2021 10:19:18
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User accepted default value 'Day 7 (Day 7)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:33:05

US3912163

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 10:19:18

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	15 Mar 2021 18:51:37
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:35:34
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:33:05

US3912163

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 10:19:18

Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	15 Mar 2021 18:51:37
User closed query 'Per source: Please add Saliva Sample D9 dated 18Dec2020, Saliva Sample D14 dated 23Dec2020 and Saliva Sample D21 dated 31Dec2020 to EDC. ' (Site from CRA).	(b) (4), (b) (6)	13 Jan 2021 20:41:08
Query 'Per source: Please add Saliva Sample D9 dated 18Dec2020, Saliva Sample D14 dated 23Dec2020 and Saliva Sample D21 dated 31Dec2020 to EDC. ' answered with 'saliva log updated' (Site from CRA).	Sandra Clancy (b) (4) (b) (4)	12 Jan 2021 00:00:58
User opened query 'Per source: Please add Saliva Sample D9 dated 18Dec2020, Saliva Sample D14 dated 23Dec2020 and Saliva Sample D21 dated 31Dec2020 to EDC. ' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 17:37:21
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:35:34
User entered '16 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:33:05

US3912163

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:19:18

Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User accepted default value 'Day 9 (Day 9)'	Sandra Clancy (b) (4) (b) (4)	12 Jan 2021 00:01:49

US3912163

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:19:18

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User signature succeeded.	Mark Hutchens (b) (4)	15 Mar 2021 18:51:37
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:41:18
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	12 Jan 2021 00:01:49

US3912163

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:19:18

Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	15 Mar 2021 18:51:37
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:41:18
User entered '18 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	12 Jan 2021 00:01:49

US3912163

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:19:18

Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User accepted default value 'Day 14 (Day 14)'	Sandra Clancy (b) (4) (b) (4)	12 Jan 2021 00:02:13

US3912163

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:19:18

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	15 Mar 2021 18:51:37
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:41:18
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	12 Jan 2021 00:02:13

US3912163

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:19:18

Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	15 Mar 2021 18:51:37
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:41:18
User entered '23 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	12 Jan 2021 00:02:13

US3912163
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 10 Jun 2021 10:19:18
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User accepted default value 'Day 21 (Day 21)'	Sandra Clancy (b) (4) (b) (4)	12 Jan 2021 00:02:36

US3912163

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 10:19:18

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	15 Mar 2021 18:51:37
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:41:18
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	12 Jan 2021 00:02:36

US3912163

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 10:19:18

Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	15 Mar 2021 18:51:37
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:41:18
User entered '31 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	12 Jan 2021 00:02:36

US3912163

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:19:18

Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User accepted default value 'Day 28 (Day 28)'	Sandra Clancy (b) (4) (b) (4)	12 Jan 2021 00:02:58

US3912163

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:19:18

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	15 Mar 2021 18:51:37
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:41:18
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	12 Jan 2021 00:02:58

US3912163

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:19:18

Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 05JAN2021 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number and tracking number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 20:01:43
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	15 Mar 2021 18:51:37
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 05JAN2021 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number and tracking number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'confirmed shipment; req. number: 1F635862742; results received 19Jan2021.' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	15 Mar 2021 18:26:52
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 05JAN2021 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number and tracking number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 07:57:33
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:41:18
User entered '5 Jan 2021'	Sandra Clancy (b) (4) (b) (4)	12 Jan 2021 00:02:58

US3912163
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:19:18
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
User closed query 'Please enter data for Convalescent Visit Day 28. Thank you!' (Site from CRA).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:41:57
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 23DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 06:21:50
Query 'Please enter data for Convalescent Visit Day 28. Thank you!' answered with 'data has been entered' (Site from CRA).	Sandra Clancy (b) (4) (b) (4)	10 Mar 2021 20:26:08
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 23DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	10 Mar 2021 20:25:52
User opened query 'Please enter data for Convalescent Visit Day 28. Thank you!' (Site from CRA).	(b) (4), (b) (6)	11 Jan 2021 18:50:14
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:55
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 23DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 10:01:28
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:20:19

US3912163
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:19:18

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 06:21:38
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' answered with 'EDC updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	10 Mar 2021 20:26:38
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:55
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 06:36:54
User entered '10 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:20:19

US3912163

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:19:18

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:55
User entered 'Home (Home)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:20:19

US3912163
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:19:18
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User entered 'SICKD1'	System	17 Dec 2020 21:20:19

US3912163
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:34:01
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	17 Dec 2020 21:21:34

US3912163
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:33:58
User entered '10 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:21:34

US3912163

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:18

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:58:07
User closed query 'Per Illness Visit Form, Page 3 of 5, assessment time was 12:48. Please correct, or clarify. Thank you!' (Site from CRA).	(b) (4), (b) (6)	19 Jan 2021 14:58:05
Query 'Per Illness Visit Form, Page 3 of 5, assessment time was 12:48. Please correct, or clarify. Thank you!' answered with 'Data corrected' (Site from CRA).	Mia Rountree (b) (4) (b) (4)	18 Jan 2021 21:21:52
DataPoint Un-verified.	Mia Rountree (b) (4) (b) (4)	18 Jan 2021 21:21:43
User entered '12:48' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	18 Jan 2021 21:21:43
User opened query 'Per Illness Visit Form, Page 3 of 5, assessment time was 12:48. Please correct, or clarify. Thank you!' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 17:33:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:32:41
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Dec 2020 21:25:15
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	17 Dec 2020 21:25:15
User entered '12:40' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:25:15
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Dec 2020 21:21:34
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:21:34

US3912163

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:18

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User entered '10 Dec 2020 12:48'	System	18 Jan 2021 21:21:43
User entered '10 Dec 2020 12:40'	System	17 Dec 2020 21:25:15
User entered empty.	System	17 Dec 2020 21:21:34

FDA-CBER-2022-1614-3510299

US3912163
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 17:32:36
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Dec 2020 21:24:42
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	17 Dec 2020 21:24:42
User entered '71.5' in reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Dec 2020 21:24:42
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Dec 2020 21:21:34
User entered empty.	Sandra Clancy (b) (4)	17 Dec 2020 21:21:34
	(b) (4)	
DataPoint set to visible.	System	17 Dec 2020 21:20:19

US3912163

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:18

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:32:35
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Dec 2020 21:24:42
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	17 Dec 2020 21:24:42
User entered '246.2' lb reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Dec 2020 21:24:42
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Dec 2020 21:21:34
User entered empty.	Sandra Clancy (b) (4)	17 Dec 2020 21:21:34
DataPoint set to visible.	System	17 Dec 2020 21:20:19

US3912163

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:18

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:32:29
User entered '98.6' F	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:21:34

US3912163
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:32:31
User entered 'Oral (Oral)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:21:34

US3912163
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:34:03
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:21:34

US3912163
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:32:25
User entered '58'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:21:34

US3912163
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User entered 'bpm'	System	17 Dec 2020 21:21:34

US3912163
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:32:26
User entered '16'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:21:34

US3912163
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User entered 'breaths/min'	System	17 Dec 2020 21:21:34

US3912163

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:18

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User closed query 'Per CDM: Systolic Blood Pressure reported is out of range ≤ 89 or > ≥ 141 mmHg. Please confirm CS or NCS. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 06:28:08
Query 'Per CDM: Systolic Blood Pressure reported is out of range ≤ 89 or > ≥ 141 mmHg. Please confirm CS or NCS. Thank you.' answered with 'Investigator deemed NCS' (Site from DM).	Mia Rountree (b) (4) (b) (4)	01 Feb 2021 20:26:45
User opened query 'Per CDM: Systolic Blood Pressure reported is out of range ≤ 89 or > ≥ 141 mmHg. Please confirm CS or NCS. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 08:11:14
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:32:17
User entered '150'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:21:34

US3912163
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User entered 'mmHg'	System	17 Dec 2020 21:21:34

US3912163

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:18

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User closed query 'Per CDM: Diastolic Blood Pressure reported is out of range ≥ 91 mmHg. Please confirm CS or NCS. Thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 08:24:10
Query 'Per CDM: Diastolic Blood Pressure reported is out of range ≥ 91 mmHg. Please confirm CS or NCS. Thank you. ' answered with 'Investigator deemed NCS' (Site from DM).	Mia Rountree (b) (4) (b) (4)	01 Feb 2021 20:26:55
User opened query 'Per CDM: Diastolic Blood Pressure reported is out of range ≥ 91 mmHg. Please confirm CS or NCS. Thank you. ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 03:36:50
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:32:20
User entered '96'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:21:34

US3912163
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User entered 'mmHg'	System	17 Dec 2020 21:21:34

US3912163

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:18

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10

US3912163
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10

US3912163

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:19:18

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:34:12
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:25:37

Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 10:19:18

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:34:12
User entered '10 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:25:37

US3912163

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 10:19:18

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	16 Mar 2021 21:17:32
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 31DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 20:01:24
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 31DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' answered with 'sample details are entered under saliva collection eCRF day 21.' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	15 Mar 2021 18:21:44
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:34:17
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 31DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 09:21:07
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:25:45

US3912163

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 10:19:18

Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:10
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	16 Mar 2021 21:17:32
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 10 DEC 2020 is recorded under Illness Visit Day 1 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 20:01:28
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 10 DEC 2020 is recorded under Illness Visit Day 1 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'confirmed shipment completed; req. number 1F634277037; Airbill number is 10022861009100064086000936271003530.' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	15 Mar 2021 18:24:33
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:34:17
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 10 DEC 2020 is recorded under Illness Visit Day 1 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 07:02:07
User entered '10 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 21:25:45

FDA-CBER-2022-1614-3510318

US3912163
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:19:18
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:23:43
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:38:49
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:58:30

FDA-CBER-2022-1614-3510319

US3912163
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:19:18

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:23:43
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:38:49
User entered '5 Jan 2021'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:58:30

US3912163

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:19:18

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:23:43
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:38:49
User entered 'Clinic (Clinic)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:58:30

US3912163
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:19:18
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:23:43
User entered 'SICKD28'	System	11 Jan 2021 23:58:30

US3912163
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:23:43
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:39:24
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:59:22

US3912163

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:18

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:23:43
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:39:21
User entered '5 Jan 2021'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:59:22

US3912163

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:18

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:23:43
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:39:20
User entered '17:44'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:59:22

US3912163
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:23:43
User entered '5 Jan 2021 17:44'	System	11 Jan 2021 23:59:22

US3912163
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:23:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:39:18
User entered missing code ND - Not Done.	Sandra Clancy (b) (4)	11 Jan 2021 23:59:22
	(b) (4)	
DataPoint set to visible.	System	11 Jan 2021 23:58:30

US3912163

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:18

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:23:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 22:39:16
User entered missing code ND - Not Done.	Sandra Clancy (b) (4)	11 Jan 2021 23:59:22
DataPoint set to visible.	(b) (4) System	11 Jan 2021 23:58:30

US3912163
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:23:43
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:39:02
User entered '97.0' F	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:59:22

US3912163
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:23:43
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:39:13
User entered 'Oral (Oral)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:59:22

US3912163
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:23:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:39:14
User entered empty.	Sandra Clancy (b) (4)	11 Jan 2021 23:59:22

US3912163

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:18

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:23:43
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:39:09
User entered '73'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:59:22

US3912163
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:23:43
User entered 'bpm'	System	11 Jan 2021 23:59:22

US3912163

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:18

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:23:43
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:39:07
User entered '16'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:59:22

US3912163
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:23:43
User entered 'breaths/min'	System	11 Jan 2021 23:59:22

US3912163

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:19:18

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:23:43
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:39:04
User entered '147'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:59:22

US3912163
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:23:43
User entered 'mmHg'	System	11 Jan 2021 23:59:22

US3912163
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:23:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 22:39:05
User entered '90'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:59:22

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:23:43
User entered 'mmHg'	System	11 Jan 2021 23:59:22

FDA-CBER-2022-1614-3510339

Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:23:43

FDA-CBER-2022-1614-3510340

US3912163
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:19:18
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:23:43

US3912163

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:19:18

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:23:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 22:39:34
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:59:33

US3912163
Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 10:19:18
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:23:43
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:39:34
User entered '5 Jan 2021'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:59:33

US3912163

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 10:19:18

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:23:43
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	29 Mar 2021 22:39:22
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:39:42
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:59:49

FDA-CBER-2022-1614-3510344

US3912163

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 10:19:18

Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:23:43
User closed query 'Per GCL Lab Recon: SARS-COV2: Sample dated 05 JAN 2021 is missing in PPD GCL records, please kindly review the preclarus and update the PPD GCL with missing sample data and also provide the Accession number, Tracking number & shipping date, as this helps to track the sample with the details provided. Please kindly also review if site has to scan in barcodes through preclarus, so that the data reflects in PPD GCL records. Thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 07:57:20
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	29 Mar 2021 22:39:22
Query 'Per GCL Lab Recon: SARS-COV2: Sample dated 05 JAN 2021 is missing in PPD GCL records, please kindly review the preclarus and update the PPD GCL with missing sample data and also provide the Accession number, Tracking number & shipping date, as this helps to track the sample with the details provided. Please kindly also review if site has to scan in barcodes through preclarus, so that the data reflects in PPD GCL records. Thank you. ' answered with 'Per Pleclarus received report. GCL received sample Sars-COV-2 - 1 and 2 on 07 Jan 2021 and Sars-COV-2 - 3 and 4 on 14 Jan 2021.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 23:45:25
User opened query 'Per GCL Lab Recon: SARS-COV2: Sample dated 05 JAN 2021 is missing in PPD GCL records, please kindly review the preclarus and update the PPD GCL with missing sample data and also provide the Accession number, Tracking number & shipping date, as this helps to track the sample with the details provided. Please kindly also review if site has to scan in barcodes through preclarus, so that the data reflects in PPD GCL records. Thank you. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 12:14:44

PRODUCTION RELEASE (v12.003 EAB) (1725)

Folder: Convalescence Visit Day 28 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 10 Jun 2021 10:19:18

Date of Collection

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:39:42
User entered '5 Jan 2021'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:59:49

FDA-CBER-2022-1614-3510346

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	08 Feb 2021 17:52:56

FDA-CBER-2022-1614-3510347

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:19:18

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	29 Mar 2021 22:39:22
User closed query 'Per response, 'subject was unblinded on 05Feb2021 but unable to get injection until 26Feb2021.' Please consider updating visit date according to unblinding date/immunology assessment date if appropriate. Thank you. ' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 18:49:09
Query 'Per response, 'subject was unblinded on 05Feb2021 but unable to get injection until 26Feb2021.' Please consider updating visit date according to unblinding date/immunology assessment date if appropriate. Thank you. ' answered with 'Data updated' (Site from CRA).	Mia Rountree (b) (4) (b) (4)	29 Mar 2021 18:46:12
Signature has been broken.	Mia Rountree (b) (4) (b) (4)	29 Mar 2021 18:46:06
User entered '05 Feb 2021' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	29 Mar 2021 18:46:06
User opened query 'Per response, 'subject was unblinded on 05Feb2021 but unable to get injection until 26Feb2021.' Please consider updating visit date according to unblinding date/immunology assessment date if appropriate. Thank you. ' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 16:00:19
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:36
Signature has been broken.	Mia Rountree (b) (4) (b) (4)	01 Mar 2021 17:58:30
User entered '26 Feb 2021' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	01 Mar 2021 17:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '5 Feb 2021'	Tina Rountree (b) (4) (b) (4)	08 Feb 2021 17:52:56

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:19:18

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Clinic (Clinic)'	Tina Rountree (b) (4) (b) (4)	08 Feb 2021 17:52:56

US3912163
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:19:18
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User entered 'UNBLND_DECIDE'	System	08 Feb 2021 17:52:56

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:19:18

Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:36
User closed query 'Per source documentation, subject was consented on 05Feb2021. Please correct. ' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 19:54:17
Query 'Per source documentation, subject was consented on 05Feb2021. Please correct. ' answered with 'Data corrected' (Site from CRA).	Mia Rountree (b) (4) (b) (4)	08 Mar 2021 17:41:49
User entered '05 Feb 2021' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	08 Mar 2021 17:40:24
User opened query 'Per source documentation, subject was consented on 05Feb2021. Please correct. ' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 19:13:55
Signature has been broken.	Mia Rountree (b) (4) (b) (4)	01 Mar 2021 17:58:46
User entered '26 Feb 2021' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	01 Mar 2021 17:58:46
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '5 Feb 2021'	Tina Rountree (b) (4) (b) (4)	08 Feb 2021 17:53:28

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:19:18

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:36
User entered '0'	Mia Rountree (b) (4) (b) (4)	08 Mar 2021 17:40:24
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:26:11

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:19:18

Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	08 Feb 2021 17:53:28

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:19:18

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:36
User entered 'Amendment 6 or later (Amendment 6 or later)'	Mia Rountree (b) (4) (b) (4)	08 Mar 2021 17:40:24
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:26:11

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:19:18

Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:36
User closed query 'Per Endpoint IRT, subject was unblinded on 05Feb2021. Please correct. ' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 19:54:19
Query 'Per Endpoint IRT, subject was unblinded on 05Feb2021. Please correct. ' answered with 'Data corrected ' (Site from CRA).	Mia Rountree (b) (4) (b) (4)	08 Mar 2021 17:42:09
User entered '05 Feb 2021' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	08 Mar 2021 17:40:24
User opened query 'Per Endpoint IRT, subject was unblinded on 05Feb2021. Please correct. ' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 19:12:55
Signature has been broken.	Mia Rountree (b) (4) (b) (4)	01 Mar 2021 17:58:46
User entered '26 Feb 2021' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	01 Mar 2021 17:58:46
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '5 Feb 2021'	Tina Rountree (b) (4) (b) (4)	08 Feb 2021 17:53:28

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:19:18

Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Placebo (Placebo)'	Tina Rountree (b) (4) (b) (4)	08 Feb 2021 17:53:28

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:19:18

Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Placebo (Placebo)'	Tina Rountree (b) (4) (b) (4)	08 Feb 2021 17:53:28

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:19:18

Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Placebo (Placebo)'	Tina Rountree (b) (4) (b) (4)	08 Feb 2021 17:53:28

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:19:18

Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User closed query 'Per source documentation, subject received mRNA-1273 on 26Feb2021. Please update and add details to Exposure page. ' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 20:20:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:36
Query 'Per source documentation, subject received mRNA-1273 on 26Feb2021. Please update and add details to Exposure page. ' answered with 'updated data' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 15:45:59
Signature has been broken.	(b) (4), (b) (6)	09 Mar 2021 15:45:49
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 15:45:49
User opened query 'Per source documentation, subject received mRNA-1273 on 26Feb2021. Please update and add details to Exposure page. ' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 19:14:28
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	08 Feb 2021 17:53:28

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:19:18

Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User entered '1'	System	08 Feb 2021 17:53:28

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:19:18

Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User entered '1'	System	09 Mar 2021 15:45:49
User entered empty.	System	08 Feb 2021 17:53:28

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:19:18

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:36
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 15:49:57

FDA-CBER-2022-1614-3510362

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:19:18

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:36
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 15:49:57

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User entered empty.	System	09 Mar 2021 15:49:57
DataPoint set to visible.	System	09 Mar 2021 15:45:49

FDA-CBER-2022-1614-3510364

Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 10:19:18
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:36
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 15:49:57

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:19:18

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:36
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:49:57

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:19:18

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User entered empty.	System	09 Mar 2021 15:49:57
DataPoint set to visible.	System	09 Mar 2021 15:45:49

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	09 Mar 2021 15:49:57

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:49:57

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:36
User entered '26 Feb 2021'	(b) (4), (b) (6)	09 Mar 2021 15:49:57

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:36
User entered '14:30'	(b) (4), (b) (6)	09 Mar 2021 15:49:57

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User entered '26 Feb 2021 14:30'	System	09 Mar 2021 15:49:57

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:36
User entered '98.3' F	(b) (4), (b) (6)	09 Mar 2021 15:49:57

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:36
User entered 'Oral (Oral)'	(b) (4), (b) (6)	09 Mar 2021 15:49:57

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:36
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 15:49:57

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:36
User entered '65'	(b) (4), (b) (6)	09 Mar 2021 15:49:57

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User entered 'bpm'	System	09 Mar 2021 15:49:57

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:36
User entered '12'	(b) (4), (b) (6)	09 Mar 2021 15:49:57

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User entered 'breaths/min'	System	09 Mar 2021 15:49:57

FDA-CBER-2022-1614-3510379

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:36
User entered '136'	(b) (4), (b) (6)	09 Mar 2021 15:49:57

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User entered 'mmHg'	System	09 Mar 2021 15:49:57

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:36
User entered '88'	(b) (4), (b) (6)	09 Mar 2021 15:49:57

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User entered 'mmHg'	System	09 Mar 2021 15:49:57

FDA-CBER-2022-1614-3510383

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:36
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 15:49:57

FDA-CBER-2022-1614-3510384

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:19:18

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:36
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 15:49:57

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:19:18

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User entered empty.	System	09 Mar 2021 15:49:57
DataPoint set to visible.	System	09 Mar 2021 15:45:49

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	09 Mar 2021 15:49:57

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 15:49:57

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:36
User entered '26 Feb 2021'	(b) (4), (b) (6)	09 Mar 2021 15:49:57

Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:19:18

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:36
User entered '16:42'	(b) (4), (b) (6)	09 Mar 2021 15:49:57

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User entered '26 Feb 2021 16:42'	System	09 Mar 2021 15:49:57

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:36
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:49:57

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:36
User entered 'Oral (Oral)'	(b) (4), (b) (6)	09 Mar 2021 15:49:57

FDA-CBER-2022-1614-3510393

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:36
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 15:49:57

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:36
User entered '64'	(b) (4), (b) (6)	09 Mar 2021 15:49:57

FDA-CBER-2022-1614-3510395

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User entered 'bpm'	System	09 Mar 2021 15:49:57

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:36
User entered '12'	(b) (4), (b) (6)	09 Mar 2021 15:49:57

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User entered 'breaths/min'	System	09 Mar 2021 15:49:57

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:36
User entered '135'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:49:57

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User entered 'mmHg'	System	09 Mar 2021 15:49:57

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:36
User entered '92'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:49:57

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User entered 'mmHg'	System	09 Mar 2021 15:49:57

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:47:07

FDA-CBER-2022-1614-3510403

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:19:18

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:36
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:47:07

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:19:18

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 15:46:34

FDA-CBER-2022-1614-3510405

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:35
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:46:34

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:19:18

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:35
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:46:34

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:19:18

What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User entered 'mRNA-1273'	System	09 Mar 2021 15:46:34
DataPoint set to visible.	System	09 Mar 2021 15:45:49

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:19:18

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:35
User entered '26 Feb 2021'	(b) (4), (b) (6)	09 Mar 2021 15:46:34

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:19:18

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
User entered '15:05'	(b) (4), (b) (6)	09 Mar 2021 15:46:34

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:19:18

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User entered '26 Feb 2021 15:05'	System	09 Mar 2021 15:46:34

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:19:18

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:35
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:46:34

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:19:18

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User entered 'ONCE'	System	09 Mar 2021 15:46:34

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:19:18

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User entered 'INTRAMUSCULAR'	System	09 Mar 2021 15:46:34

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:18

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	29 Mar 2021 22:39:22
User closed query 'Per query response, please add details for Immunogenicity sample collected at Decision Visit dated 05Feb2021. Thank you!' (Site from CRA).	(b) (4), (b) (6)	15 Mar 2021 18:33:05
Query 'Per query response, please add details for Immunogenicity sample collected at Decision Visit dated 05Feb2021. Thank you!' answered with 'updated' (Site from CRA).	Sandra Clancy (b) (4) (b) (4)	15 Mar 2021 18:30:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	15 Mar 2021 18:30:14
User opened query 'Per query response, please add details for Immunogenicity sample collected at Decision Visit dated 05Feb2021. Thank you!' (Site from CRA).	(b) (4), (b) (6)	11 Mar 2021 14:19:33
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 05 FEB 2021 is reported under Participant Decision Visit OL-D1/OL-1 visit in PPD Central lab; however, the same Immunogenicity sample is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 13:15:40
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 05 FEB 2021 is reported under Participant Decision Visit OL-D1/OL-1 visit in PPD Central lab; however, the same Immunogenicity sample is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'Immunogenicity sample collected at Decision Visit dated 05Feb2021; Decision visit and OL-D1 visit did not occurred on the same day' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	10 Mar 2021 20:30:27

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:18

Was the sample collected?

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 05 FEB 2021 is reported under Participant Decision Visit OL-D1/OL-1 visit in PPD Central lab; however, the same Immunogenicity sample is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 05:34:19
Signature has been broken.	Mia Rountree (b) (4) (b) (4)	01 Mar 2021 17:59:28
User entered 'No (N)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	01 Mar 2021 17:59:28
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	08 Feb 2021 17:58:26

FDA-CBER-2022-1614-3510416

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:18

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	29 Mar 2021 22:39:22
User closed query 'The Collection Date is prior to the Participant Decision Visit Date. Please review and reconcile.' (Site from System).	System	29 Mar 2021 18:46:06
User opened query 'The Collection Date is prior to the Participant Decision Visit Date. Please review and reconcile.' (Site from System).	System	15 Mar 2021 18:30:14
User entered '5 Feb 2021' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	15 Mar 2021 18:30:14
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	01 Mar 2021 17:59:28
User closed query 'The Collection Date is before the Date of Updated Informed Consent. Please review and reconcile.' (Site from System).	System	01 Mar 2021 17:58:56
User closed query 'The Collection Date is prior to the Participant Decision Visit Date. Please review and reconcile.' (Site from System).	System	01 Mar 2021 17:58:56
Signature has been broken.	Mia Rountree (b) (4) (b) (4)	01 Mar 2021 17:58:56
User entered '26 Feb 2021' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	01 Mar 2021 17:58:56
User opened query 'The Collection Date is before the Date of Updated Informed Consent. Please review and reconcile.' (Site from System).	System	01 Mar 2021 17:58:46
User opened query 'The Collection Date is prior to the Participant Decision Visit Date. Please review and reconcile.' (Site from System).	System	01 Mar 2021 17:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '5 Feb 2021'	Tina Rountree (b) (4) (b) (4)	08 Feb 2021 17:58:26

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	29 Mar 2021 22:39:22
User entered '14:37' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	15 Mar 2021 18:30:14
Signature has been broken.	Mia Rountree (b) (4) (b) (4)	01 Mar 2021 17:59:28
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	01 Mar 2021 17:59:28
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '14:37'	Tina Rountree (b) (4) (b) (4)	08 Feb 2021 17:58:26

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:19:18

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User entered '5 Feb 2021 14:37'	System	15 Mar 2021 18:30:14
User entered empty.	System	01 Mar 2021 17:59:28
User entered '26 Feb 2021 14:37'	System	01 Mar 2021 17:58:56
User entered '5 Feb 2021 14:37'	System	08 Feb 2021 17:58:26

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:19:18

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	15 Mar 2021 18:51:37
User closed query 'Per query response, please add details for NP sample collected at Decision Visit dated 05Feb2021. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	15 Mar 2021 18:33:11
Query 'Per query response, please add details for NP sample collected at Decision Visit dated 05Feb2021. Thank you! ' answered with 'updated' (Site from CRA).	Sandra Clancy (b) (4) (b) (4)	15 Mar 2021 18:32:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	15 Mar 2021 18:29:42
User closed query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 05-Feb-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 11:42:21
User opened query 'Per query response, please add details for NP sample collected at Decision Visit dated 05Feb2021. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	11 Mar 2021 14:19:58
Query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 05-Feb-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' answered with 'sample collected 05Feb2021 under Decision Visit; Decision Visit and OL-D1 occurred on 2 different days.' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	10 Mar 2021 20:29:18

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:19:18

Was the sample collected?

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 05-Feb-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 05:54:49
Signature has been broken.	Mia Rountree (b) (4) (b) (4)	01 Mar 2021 17:59:46
User entered 'No (N)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	01 Mar 2021 17:59:46
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	08 Feb 2021 17:58:41

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:19:18

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	15 Mar 2021 18:51:37
User entered '5 Feb 2021' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	15 Mar 2021 18:29:42
User closed query 'The Collection Date is before the Date of Updated Informed consent. Please review and reconcile.' (Site from System).	System	01 Mar 2021 17:59:46
Signature has been broken.	Mia Rountree (b) (4) (b) (4)	01 Mar 2021 17:59:46
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	01 Mar 2021 17:59:46
User opened query 'The Collection Date is before the Date of Updated Informed consent. Please review and reconcile.' (Site from System).	System	01 Mar 2021 17:58:46
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '5 Feb 2021'	Tina Rountree (b) (4) (b) (4)	08 Feb 2021 17:58:41

Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 10:19:18
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	15 Mar 2021 18:51:37
User entered '14:39' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	15 Mar 2021 18:29:42
Signature has been broken.	Mia Rountree (b) (4) (b) (4)	01 Mar 2021 17:59:46
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4) (b) (4)	01 Mar 2021 17:59:46
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '14:39'	Tina Rountree (b) (4) (b) (4)	08 Feb 2021 17:58:41

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:19:18

Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User entered '5 Feb 2021 14:39'	System	15 Mar 2021 18:29:42
User entered empty.	System	01 Mar 2021 17:59:46
User entered '5 Feb 2021 14:39'	System	08 Feb 2021 17:58:41

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:18

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:58:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 15:50:12

US3912163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:18

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:10:39
User entered '1'	System	09 Mar 2021 15:50:12

US3912163
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:19:18

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:22
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:50:37

US3912163

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:18

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:22
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:36
User entered '5 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:50:37

US3912163
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:19:18
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:22
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:50:37

US3912163

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:18

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:22
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:36
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:50:37

US3912163

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:18

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:22
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:58:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:50:47

US3912163

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:18

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:22
User entered '1'	System	09 Mar 2021 15:50:47

US3912163
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:19:18
OLD29 Placebo Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:22
User entered '1'	System	09 Mar 2021 15:50:47
DataPoint set to visible.	System	09 Mar 2021 15:50:47

US3912163
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:19:18
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	29 Mar 2021 22:39:22
User entered 'Yes (Y)'	Monique Gawlik (b) (4)	26 Mar 2021 22:59:44

US3912163
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:19:18

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User signature succeeded.	Mark Hutchens (b) (4)	29 Mar 2021 22:39:22
User entered '26 Mar 2021'	Monique Gawlik (b) (4)	26 Mar 2021 22:59:44

US3912163
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:19:18

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User signature succeeded.	Mark Hutchens (b) (4)	29 Mar 2021 22:39:22
User entered 'Clinic (Clinic)'	Monique Gawlik (b) (4)	26 Mar 2021 22:59:44

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User entered 'OLD29'	System	26 Mar 2021 22:59:44

FDA-CBER-2022-1614-3510437

US3912163

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User accepted default value 'Pre-Dose (PREDOSE)'	Monique Gawlik (b) (4)	26 Mar 2021 23:02:10

US3912163

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	29 Mar 2021 22:39:22
User entered 'Yes (Y)'	Monique Gawlik (b) (4)	26 Mar 2021 23:02:10

US3912163

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	29 Mar 2021 22:39:22
User entered '26 Mar 2021'	Monique Gawlik (b) (4)	26 Mar 2021 23:02:10

US3912163

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User signature succeeded.	Mark Hutchens (b) (4)	29 Mar 2021 22:39:22
	(b) (4)	
User entered '14:47'	Monique Gawlik (b) (4)	26 Mar 2021 23:02:10

US3912163

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User entered '26 Mar 2021 14:47'	System	26 Mar 2021 23:02:10

US3912163

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	29 Mar 2021 22:39:22
User entered '97.9' F	Monique Gawlik (b) (4)	26 Mar 2021 23:02:10

US3912163

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User signature succeeded.	Mark Hutchens (b) (4)	29 Mar 2021 22:39:22
	(b) (4)	
User entered 'Oral (Oral)'	Monique Gawlik (b) (4)	26 Mar 2021 23:02:10

US3912163
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:19:18
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User signature succeeded.	Mark Hutchens (b) (4)	29 Mar 2021 22:39:22
User entered empty.	Monique Gawlik (b) (4)	26 Mar 2021 23:02:10

US3912163
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:19:18
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	29 Mar 2021 22:39:22
User entered '70'	Monique Gawlik (b) (4)	26 Mar 2021 23:02:10

US3912163
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:19:18
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User entered 'bpm'	System	26 Mar 2021 23:02:10

US3912163

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:19:18

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	29 Mar 2021 22:39:22
User entered '16'	Monique Gawlik (b) (4)	26 Mar 2021 23:02:10

US3912163
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:19:18
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User entered 'breaths/min'	System	26 Mar 2021 23:02:10

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User signature succeeded.	Mark Hutchens (b) (4)	29 Mar 2021 22:39:22
User entered '139'	Monique Gawlik (b) (4)	26 Mar 2021 23:02:10

US3912163
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:19:18
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User entered 'mmHg'	System	26 Mar 2021 23:02:10

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	29 Mar 2021 22:39:22
User entered '95'	Monique Gawlik (b) (4)	26 Mar 2021 23:02:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User entered 'mmHg'	System	26 Mar 2021 23:02:10

FDA-CBER-2022-1614-3510453

US3912163
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:19:18
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User accepted default value 'Post-Dose (POSTDOSE)'	Monique Gawlik (b) (4)	26 Mar 2021 23:02:10

US3912163

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	29 Mar 2021 22:39:22
User entered 'Yes (Y)'	Monique Gawlik (b) (4)	26 Mar 2021 23:02:10

US3912163

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	29 Mar 2021 22:39:22
User entered '26 Mar 2021'	Monique Gawlik (b) (4)	26 Mar 2021 23:02:10

US3912163

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	29 Mar 2021 22:39:22
User entered '16:35'	Monique Gawlik (b) (4)	26 Mar 2021 23:02:10

US3912163

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User entered '26 Mar 2021 16:35'	System	26 Mar 2021 23:02:10

US3912163
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:19:18

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	29 Mar 2021 22:39:22
User entered '99.1' F	Monique Gawlik (b) (4)	26 Mar 2021 23:02:10

US3912163

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User signature succeeded.	Mark Hutchens (b) (4)	29 Mar 2021 22:39:22
User entered 'Oral (Oral)'	Monique Gawlik (b) (4)	26 Mar 2021 23:02:10

US3912163
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:19:18
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User signature succeeded.	Mark Hutchens (b) (4)	29 Mar 2021 22:39:22
User entered empty.	Monique Gawlik (b) (4)	26 Mar 2021 23:02:10

US3912163

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	29 Mar 2021 22:39:22
User entered '55'	Monique Gawlik (b) (4)	26 Mar 2021 23:02:10

US3912163

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User entered 'bpm'	System	26 Mar 2021 23:02:10

US3912163

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	29 Mar 2021 22:39:22
User entered '14'	Monique Gawlik (b) (4)	26 Mar 2021 23:02:10

US3912163
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:19:18
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User entered 'breaths/min'	System	26 Mar 2021 23:02:10

US3912163

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	29 Mar 2021 22:39:22
User entered '150'	Monique Gawlik (b) (4)	26 Mar 2021 23:02:10

US3912163

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User entered 'mmHg'	System	26 Mar 2021 23:02:10

US3912163

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:19:18

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	29 Mar 2021 22:39:22
User entered '96'	Monique Gawlik (b) (4)	26 Mar 2021 23:02:10

US3912163
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:19:18
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User entered 'mmHg'	System	26 Mar 2021 23:02:10

US3912163

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:19:18

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User signature succeeded.	Mark Hutchens (b) (4)	29 Mar 2021 22:39:22
User entered 'Yes (Y)'	Monique Gawlik (b) (4)	26 Mar 2021 23:02:18

US3912163

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:19:18

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	29 Mar 2021 22:39:22
User entered '26 Mar 2021'	Monique Gawlik (b) (4)	26 Mar 2021 23:02:18

US3912163
Folder: OL-D29 (1)
Form: Exposure
Generated On: 10 Jun 2021 10:19:18
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User signature succeeded.	Mark Hutchens (b) (4)	29 Mar 2021 22:39:22
User entered 'Yes (Y)'	Monique Gawlik (b) (4)	26 Mar 2021 23:03:14

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User signature succeeded.	Mark Hutchens (b) (4)	29 Mar 2021 22:39:22
User entered empty.	Monique Gawlik (b) (4)	26 Mar 2021 23:03:14

US3912163

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:19:18

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User signature succeeded.	Mark Hutchens (b) (4)	29 Mar 2021 22:39:22
User entered empty.	Monique Gawlik (b) (4)	26 Mar 2021 23:03:14

US3912163
Folder: OL-D29 (1)
Form: Exposure
Generated On: 10 Jun 2021 10:19:18

What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User entered 'mRNA-1273'	System	26 Mar 2021 23:03:14
DataPoint set to visible.	System	09 Mar 2021 15:50:47

US3912163

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:19:18

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	29 Mar 2021 22:39:22
User entered '26 Mar 2021'	Monique Gawlik (b) (4)	26 Mar 2021 23:03:14

US3912163

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:19:18

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User signature succeeded.	Mark Hutchens (b) (4)	29 Mar 2021 22:39:22
	(b) (4)	
User entered '15:58'	Monique Gawlik (b) (4)	26 Mar 2021 23:03:14

US3912163
Folder: OL-D29 (1)
Form: Exposure
Generated On: 10 Jun 2021 10:19:18
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User entered '26 Mar 2021 15:58'	System	26 Mar 2021 23:03:14

US3912163
Folder: OL-D29 (1)
Form: Exposure
Generated On: 10 Jun 2021 10:19:18
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User signature succeeded.	Mark Hutchens (b) (4)	29 Mar 2021 22:39:22
User entered 'Left Arm (LEFT ARM)'	Monique Gawlik (b) (4)	26 Mar 2021 23:03:14

US3912163
Folder: OL-D29 (1)
Form: Exposure
Generated On: 10 Jun 2021 10:19:18
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User entered 'ONCE'	System	26 Mar 2021 23:03:14

US3912163
Folder: OL-D29 (1)
Form: Exposure
Generated On: 10 Jun 2021 10:19:18
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User entered 'INTRAMUSCULAR'	System	26 Mar 2021 23:03:14

US3912163

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:18

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User signature succeeded.	Mark Hutchens (b) (4)	29 Mar 2021 22:39:22
User entered 'Yes (Y)'	Monique Gawlik (b) (4)	26 Mar 2021 23:03:22

US3912163
Folder: OL-D29 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:19:18
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:05
User entered '1'	System	26 Mar 2021 23:03:22

US3912163

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:18

Was Contact Attempted?

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	05 Apr 2021 00:37:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Apr 2021 20:16:38

US3912163

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:18

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	05 Apr 2021 00:37:59
User entered '2 Apr 2021'	(b) (4), (b) (6)	02 Apr 2021 20:16:38

US3912163

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:19:18

Please select one status for the follow-up contact

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	05 Apr 2021 00:37:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Apr 2021 20:16:38

US3912163
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:19:18
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 00:37:59
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 20:16:38

US3912163

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:19:18

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	05 Apr 2021 00:37:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Apr 2021 20:16:44

US3912163
Folder: Safety Call OL-D36 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:19:18
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	02 Apr 2021 20:16:44

US3912163
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 10 Jun 2021 10:19:18

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:00:57
User closed query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 145, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 08:51:45
Query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 145, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'there is SAE of NSTEMI - see AE log' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	07 Apr 2021 19:07:45
User opened query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 145, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 04:21:38
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:38:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 13:53:57

US3912163
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:19:18
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18

US3912163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:18

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:32
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 13:56:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 13:56:35
Data point term sent to Coder	System	22 Sep 2020 13:55:37
User entered 'diarrhea'	(b) (4), (b) (6)	22 Sep 2020 13:54:41

US3912163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:18

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:32
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 13:54:41

US3912163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:18

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:21:32
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 13:54:41

US3912163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:18

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:32
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 13:54:41

US3912163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:18

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:32
User entered '15 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 13:54:41

US3912163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:18

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:32
User entered '17:00'	(b) (4), (b) (6)	22 Sep 2020 13:54:41

US3912163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:18

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18
User entered '15 Sep 2020 17:00'	System	22 Sep 2020 13:54:41

US3912163
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:19:18
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:32
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Oct 2020 00:01:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Oct 2020 00:01:48
User entered 'No (N)' reason for change: Data Entry Error	Tina Rountree (b) (4)	06 Oct 2020 00:01:48
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 13:54:41
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 13:54:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:18

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:21:32
User entered '16 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 13:54:41

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:32
User entered '18:00'	(b) (4), (b) (6)	22 Sep 2020 13:54:41

US3912163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:18

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18
User entered '16 Sep 2020 18:00'	System	22 Sep 2020 13:54:41

US3912163
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:19:18
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:32
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Oct 2020 00:21:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Oct 2020 00:21:34
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Timothy Vachris (b) (4) (b) (4)	06 Oct 2020 00:21:34
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 13:54:41
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 13:54:41

US3912163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:18

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:32
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 13:54:41

US3912163
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:19:18
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:21:32
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 13:54:41

US3912163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:18

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:21:32
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 13:54:41

US3912163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:18

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:32
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 13:54:41

US3912163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:18

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:21:32
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 13:54:41

US3912163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:18

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:21:32
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 13:54:41

US3912163
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:19:18
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:21:32
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 13:54:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:18

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:32
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 13:54:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:18

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:32
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 13:54:41

US3912163
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:19:18
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:32
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 13:54:41

US3912163
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:19:18
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:32
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 13:54:41

US3912163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:18

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:32
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Oct 2020 00:22:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Oct 2020 00:22:19
User entered 'Related (RELATED)' reason for change: Data Entry Error	Timothy Vachris (b) (4)	06 Oct 2020 00:22:19
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 13:54:41
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 13:54:41

FDA-CBER-2022-1614-3510515

US3912163
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:19:18
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:21:32
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	22 Sep 2020 13:54:41

US3912163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:18

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:21:32
User entered 'None (NONE)'	(b) (4), (b) (6)	22 Sep 2020 13:54:41

US3912163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:18

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:32
User entered '1'	(b) (4), (b) (6)	22 Sep 2020 13:54:41

US3912163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:18

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:32
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 13:54:41

US3912163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:18

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:32
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 13:54:41

US3912163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:18

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	22 Sep 2020 13:54:41

US3912163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:18

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:32
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 13:54:41

US3912163
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:19:18
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:21:32
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 13:54:41

US3912163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:19:18

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18
User entered '0'	System	22 Sep 2020 13:54:41

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18
User entered '0'	System	22 Sep 2020 13:54:41

FDA-CBER-2022-1614-3510525

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:18

US3912163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:19:18
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21

US3912163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:19:18

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:30
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 15:03:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 15:03:35
Data point term sent to Coder	System	19 Oct 2020 15:02:48
User entered 'Worsening of Hypertension'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:01:53

US3912163

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:18

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:30
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:01:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:18

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:30
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:01:53

US3912163

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:18

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:30
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:01:53

US3912163

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:18

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:30
User entered '13 Oct 2020'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:01:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:18

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:30
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Oct 2020 15:02:21
User entered '09:55' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:02:21
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Oct 2020 15:01:53
User entered empty.	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:01:53

US3912163

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:18

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21
User entered '13 Oct 2020 09:55'	System	19 Oct 2020 15:02:21
User entered empty.	System	19 Oct 2020 15:01:53

US3912163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:19:18
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:30
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:01:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:18

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:30
User entered '13 Oct 2020'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:01:53

US3912163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:19:18

End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:30
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Oct 2020 15:02:21
User entered '10:07' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:02:21
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Oct 2020 15:01:53
User entered empty.	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:01:53

US3912163

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:18

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21
User entered '13 Oct 2020 10:07'	System	19 Oct 2020 15:02:21
User entered empty.	System	19 Oct 2020 15:01:53

US3912163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:19:18
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:30
User entered 'Grade 3/Severe (Grade 3/Severe)'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:01:53

US3912163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:19:18
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:30
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:01:53

US3912163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:19:18
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:30
User entered '0'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:01:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:18

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:30
User entered '0'	Mia Rountree (b) (4)	19 Oct 2020 15:01:53

US3912163

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:18

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:30
User entered '0'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:01:53

US3912163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:19:18

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:30
User entered empty.	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:01:53

US3912163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:19:18

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:30
User entered empty.	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:01:53

US3912163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:19:18
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:30
User entered empty.	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:01:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:18

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:30
User entered empty.	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:01:53

US3912163

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:18

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:30
User entered '0'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:01:53

US3912163

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:18

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:30
User entered '0'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:01:53

US3912163

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:18

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:30
User entered '0'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:01:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:18

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:30
User entered 'Not Related (NOT RELATED)'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:01:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:18

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:30
User entered 'Not Related (NOT RELATED)'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:01:53

US3912163

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:18

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:30
User entered 'Not Applicable (NOT APPLICABLE)'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:01:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:18

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:30
User entered '1'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:01:53

US3912163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:19:18
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:30
User entered '0'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:01:53

US3912163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:19:18
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:30
User entered '0'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:01:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:18

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:01:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:18

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:30
User entered empty.	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:01:53

US3912163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:19:18
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:21:30
User entered empty.	Mia Rountree (b) (4) (b) (4)	19 Oct 2020 15:01:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:18

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21
User entered '0'	System	19 Oct 2020 15:01:53

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21
User entered '0'	System	19 Oct 2020 15:01:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:19:18

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:18

AEID

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:38:19
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:14:27
User entered 'USA-US211-2020-mRNA-1273-P301000008'	System	17 Dec 2020 18:14:10
User entered 'New'	(b) (4), (b) (6)	17 Dec 2020 18:14:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:18

Adverse event

Audit	User	Time (GMT)
User closed query 'Per MM: please review and split the event as: 1. SYMPTOMATIC COVID-19 2. BODY ACHES 3. NASAL CONGESTION 4. COUGH ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 08:07:36
Query 'Per MM: please review and split the event as: 1. SYMPTOMATIC COVID-19 2. BODY ACHES 3. NASAL CONGESTION 4. COUGH ' answered with 'this was how we were asked to prepare the event in EDC--to list as symp. covid with the symptoms noted. No separate AEs are required as they are all covered and listed under the Illness Visit resulting from this diagnosis.' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	07 Apr 2021 19:04:52
User opened query 'Per MM: please review and split the event as: 1. SYMPTOMATIC COVID-19 2. BODY ACHES 3. NASAL CONGESTION 4. COUGH ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 09:44:58
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:01
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 11:35:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 11:35:56
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
Data point term sent to Coder	System	10 Mar 2021 20:11:17
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	10 Mar 2021 20:10:53
Coding entries removed.	Sandra Clancy (b) (4) (b) (4)	10 Mar 2021 20:10:53

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:18

Adverse event

Audit	User	Time (GMT)
User entered 'SYMPTOMATIC COVID-19 (symptoms of body aches,nasal congestion,cough)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	10 Mar 2021 20:10:53
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:38:21
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Dec 2020 15:20:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Dec 2020 15:20:41
Data point term sent to Coder	System	17 Dec 2020 15:19:26
User entered 'symptomatic Covid-19'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:18:33

FDA-CBER-2022-1614-3510565

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:18

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:38:22
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:18:33

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:18

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:38:24
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:18:33

FDA-CBER-2022-1614-3510567

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:18

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:38:25
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:18:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:18

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User closed query 'PV Query: Please update the event start date to reflect the date of onset of symptoms or date of positive test (both reported as reported as 10 Dec 2020). If not, please provide additional information.' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 19:47:20
Query 'PV Query: Please update the event start date to reflect the date of onset of symptoms or date of positive test (both reported as reported as 10 Dec 2020). If not, please provide additional information.' answered with 'onset of symptoms is 04Dec2020' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	08 Jan 2021 00:30:07
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:38:37
User opened query 'PV Query: Please update the event start date to reflect the date of onset of symptoms or date of positive test (both reported as reported as 10 Dec 2020). If not, please provide additional information.' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 20:56:23
User entered '4 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:18:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:18

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:38:39
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:18:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:18

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	17 Dec 2020 15:18:33

US3912163

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:18

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:40:18
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	08 Jan 2021 00:34:44
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	08 Jan 2021 00:34:44
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:38:43
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:18:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:18

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 18:35:01
User closed query 'Per CCGs v4.0, end date of symptomatic COVID-19 should reflect when symptoms resolved. Per source documentation, symptoms ended on 22Dec2020. Please clarify or correct. Thank you!' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 18:34:57
Query 'Per CCGs v4.0, end date of symptomatic COVID-19 should reflect when symptoms resolved. Per source documentation, symptoms ended on 22Dec2020. Please clarify or correct. Thank you!' answered with 'corrected' (Site from CRA).	Sandra Clancy (b) (4)	10 Feb 2021 16:17:03
DataPoint Un-verified.	Sandra Clancy (b) (4)	10 Feb 2021 16:16:53
User entered '22 Dec 2020' reason for change: Data Entry Error	Sandra Clancy (b) (4)	10 Feb 2021 16:16:53
User opened query 'Per CCGs v4.0, end date of symptomatic COVID-19 should reflect when symptoms resolved. Per source documentation, symptoms ended on 22Dec2020. Please clarify or correct. Thank you!' (Site from CRA).	(b) (4), (b) (6)	20 Jan 2021 22:42:59
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:40:18
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 19:47:26
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'corrected' (Site from Safety).	Sandra Clancy (b) (4)	08 Jan 2021 00:37:16
DataPoint Un-verified.	Sandra Clancy (b) (4)	08 Jan 2021 00:34:44
User entered '28 Dec 2020' reason for change: Data Entry Error	Sandra Clancy (b) (4)	08 Jan 2021 00:34:44
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:38:44

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:18

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 20:56:42
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:18:33

US3912163

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:18

End time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:38:46
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:18:33

US3912163

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:18

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	17 Dec 2020 15:18:33

US3912163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 10:19:18
Severity

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:38:47
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 19:30:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Dec 2020 19:30:51
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 19:30:51
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 15:18:33
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:18:33

US3912163

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:18

Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:38:49
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:18:33

US3912163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 10:19:18
Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:38:50
User entered '0'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:18:33

US3912163

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:18

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:39:11
User entered '0'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:18:33

US3912163

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:18

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:39:14
User entered '0'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:18:33

US3912163

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:18

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:39:16
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:18:33

FDA-CBER-2022-1614-3510582

US3912163

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:18

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:39:13
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:18:33

US3912163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 10:19:18
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:39:10
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:18:33

US3912163

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:18

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:39:08
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:18:33

US3912163

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:18

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:39:07
User entered '0'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:18:33

US3912163

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:18

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:39:05
User entered '0'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:18:33

US3912163

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:18

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:39:03
User entered '0'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:18:33

US3912163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 10:19:18
Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:38:52
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible. ' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 13:54:59
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible. ' answered with 'completed' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 19:31:45
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 19:31:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Dec 2020 19:31:11
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 19:31:11
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible. ' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 18:13:43
Query '[12:53 PM] (b) (6) PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' canceled (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 18:10:04
User opened query '[12:53 PM] (b) (6) PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 18:08:59
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 15:18:33
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:18:33

US3912163

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:18

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:38:54
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 19:31:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Dec 2020 19:31:11
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 19:31:11
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 15:18:33
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:18:33

US3912163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 10:19:18
Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:40:18
User closed query 'PV Query: As subject had already received both doses of study drug prior to event onset, please update action taken to not applicable.' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 19:47:34
User closed query 'Per CDM: Action taken with investigational product is 'None', however, per CCGs Version 2.0 page 35, 'Not Applicable' should be recorded if the Adverse Event started after last dose of investigational product. Please clarify and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 09:15:05
Query 'PV Query: As subject had already received both doses of study drug prior to event onset, please update action taken to not applicable.' answered with 'corrected' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	08 Jan 2021 00:37:37
Query 'Per CDM: Action taken with investigational product is 'None', however, per CCGs Version 2.0 page 35, 'Not Applicable' should be recorded if the Adverse Event started after last dose of investigational product. Please clarify and update as appropriate. Thank you.' answered with 'corrected' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	08 Jan 2021 00:37:30
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	08 Jan 2021 00:37:06
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	08 Jan 2021 00:37:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:39:02
User opened query 'PV Query: As subject had already received both doses of study drug prior to event onset, please update action taken to not applicable.' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 20:57:05
User opened query 'Per CDM: Action taken with investigational product is 'None', however, per CCGs Version 2.0 page 35, 'Not Applicable' should be recorded if the Adverse Event started after last dose of investigational product. Please clarify and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 16:50:06

PRODUCTION RELEASE (v12.003 EAB) (1725)

Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 10:19:18
Action taken with investigational product

Audit	User	Time (GMT)
User entered 'None (NONE)'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:18:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:18

None

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:39:18
User entered '0'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:18:33

US3912163

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:18

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
User closed query 'Per DM CLR - RQ: Site's response noted. However, review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 07:11:17
Query 'Per DM CLR - RQ: Site's response noted. However, review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' answered with 'clarified event to include symptoms treated' (Site from DM).	Sandra Clancy (b) (4)	10 Mar 2021 20:11:09
User opened query 'Per DM CLR - RQ: Site's response noted. However, review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 12:38:27
User closed query 'Per CDM : Please note that Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 13:15:19
Query 'Per CDM : Please note that Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate. Thank you.' answered with 'see con meds' (Site from DM).	Sandra Clancy (b) (4)	10 Feb 2021 16:16:41
User opened query 'Per CDM : Please note that Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 10:34:26
User closed query 'Per CDM: Re-Query: Response noted as 'con meds updated' but no conmed was updated. Please update the concomitant medication page as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 11:50:46

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:18

Concomitant Medication

Audit	User	Time (GMT)
Query 'Per CDM: Re-Query: Response noted as 'con meds updated' but no conmed was updated. Please update the concomitant medication page as appropriate. Thank you.' answered with 'Medications Ibuprofen, Aspirin, Nyquil Cold & Flu, Guaifenesin, Azelastine HCL Nasal Solution, Tylenol cold and flu, and pepto-bismol were all over the counter medications taken for Symptomatic COVID-19 AE.' (Site from DM).	Mia Rountree (b) (4) (b) (4)	13 Jan 2021 15:33:18
User opened query 'Per CDM: Re-Query: Response noted as 'con meds updated' but no conmed was updated. Please update the concomitant medication page as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 16:45:04
User closed query 'Per CDM: Re-Query: Response noted. Please update the concomitant medication page as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 16:45:04
Query 'Per CDM: Re-Query: Response noted. Please update the concomitant medication page as appropriate. Thank you.' answered with 'con meds updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:51:16
User opened query 'Per CDM: Re-Query: Response noted. Please update the concomitant medication page as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 09:17:21
User closed query 'Per CDM : Please note that Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 09:17:21
Query 'Per CDM : Please note that Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate. Thank you.' answered with 'con meds to be updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	08 Jan 2021 00:37:48
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:39:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:18

Concomitant Medication

Audit	User	Time (GMT)
User opened query 'Per CDM : Please note that Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 16:52:58
User entered '1'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:18:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:18

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:39:27
User entered '0'	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:18:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:18

Outcome

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:40:18
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	08 Jan 2021 00:34:44
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	08 Jan 2021 00:34:44
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:39:26
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 22:01:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Dec 2020 22:01:10
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 22:01:10
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 15:18:33
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:18:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:18

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:39:24
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:18:33

US3912163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 10:19:18
Narrative

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:39:23
User entered empty.	Sandra Clancy (b) (4) (b) (4)	17 Dec 2020 15:18:33

US3912163

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:18

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	17 Dec 2020 15:18:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:19:18

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	17 Dec 2020 15:18:33

US3912163
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 10:19:18
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27

US3912163
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 10:19:18
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:10
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Loose stools - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:20
Data point term sent to Coder	System	21 Dec 2020 15:27:20
User entered 'Loose stools'	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:26:59

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:18

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:10
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:26:59

US3912163
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 10:19:18
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:10
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:26:59

US3912163
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 10:19:18
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:10
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:26:59

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:18

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:10
User entered '08 Dec 2020'	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:26:59

US3912163
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 10:19:18

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:10
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:26:59

US3912163

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:18

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27
User entered empty.	System	21 Dec 2020 15:26:59

US3912163
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 10:19:18
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:10
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:26:59

US3912163
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 10:19:18
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:10
User entered '08 Dec 2020'	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:26:59

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:10
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:26:59

FDA-CBER-2022-1614-3510613

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27
User entered empty.	System	21 Dec 2020 15:26:59

US3912163

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:18

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:10
User entered 'Grade 1/Mild (Grade 1/Mild)'	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:26:59

US3912163
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 10:19:18
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:10
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:26:59

US3912163
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 10:19:18
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:10
User entered '0'	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:26:59

US3912163
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 10:19:18
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:10
User entered '0'	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:26:59

US3912163

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:18

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:10
User entered '0'	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:26:59

US3912163

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:18

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:10
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:26:59

Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 10:19:18

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:10
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:26:59

US3912163
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 10:19:18
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:10
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:26:59

US3912163
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 10:19:18

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:10
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:26:59

US3912163

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:18

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:10
User entered '0'	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:26:59

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:18

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:10
User entered '0'	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:26:59

US3912163

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:18

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:10
User entered '0'	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:26:59

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:18

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:10
User entered 'Not Related (NOT RELATED)'	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:26:59

US3912163
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 10:19:18
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:10
User entered 'Not Related (NOT RELATED)'	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:26:59

US3912163

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:18

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:40:16
User closed query ' Per CDM: Action taken with investigational product is 'None', however, per CCGs Version 2.0 page 35, 'Not Applicable' should be recorded if the Adverse Event started after last dose of investigational product. Please clarify and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 11:51:38
Query ' Per CDM: Action taken with investigational product is 'None', however, per CCGs Version 2.0 page 35, 'Not Applicable' should be recorded if the Adverse Event started after last dose of investigational product. Please clarify and update as appropriate. Thank you. ' answered with 'corrected' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:26:18
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:26:01
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:26:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:10
User opened query ' Per CDM: Action taken with investigational product is 'None', however, per CCGs Version 2.0 page 35, 'Not Applicable' should be recorded if the Adverse Event started after last dose of investigational product. Please clarify and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 16:50:45
User entered 'None (NONE)'	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:26:59

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:18

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:10
User entered '1'	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:26:59

US3912163
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 10:19:18
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:10
User entered '0'	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:26:59

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:18

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:10
User entered '0'	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:26:59

US3912163

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:18

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:26:59

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:18

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:10
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:26:59

US3912163
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 10:19:18
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:10
User entered empty.	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 15:26:59

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:18

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27
User entered '0'	System	21 Dec 2020 15:26:59

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:18

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27
User entered '0'	System	21 Dec 2020 15:26:59

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:19:18

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:49:27

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:18

AEID

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:57:41
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:37
User entered 'USA-US211-2021-mRNA-1273-P301000002'	System	05 Feb 2021 13:00:06
User entered 'New'	(b) (4), (b) (6)	05 Feb 2021 13:00:06

Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:15
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Acute myocardial infarction, LLT: Non ST segment elevation myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 23:48:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 23:48:03
Data point term sent to Coder	System	10 Feb 2021 16:41:32
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:41:25
Coding entries removed.	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:41:25
User entered 'NSTEMI-non ST-elevation myocardial infarction' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:41:25
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:00:57
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Feb 2021 16:06:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Feb 2021 16:06:46
Data point term sent to Coder	System	04 Feb 2021 16:06:00
User entered 'myocardial infarction'	Monique Gawlik (b) (4)	04 Feb 2021 16:05:45

US3912163

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:18

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:56:47
User entered 'Yes (Y)'	Monique Gawlik (b) (4)	04 Feb 2021 16:05:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:18

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:56:49
User entered 'No (N)'	Monique Gawlik (b) (4)	04 Feb 2021 16:05:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:18

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:01:21
User entered 'No (N)'	Monique Gawlik (b) (4)	04 Feb 2021 16:05:45

US3912163

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:18

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:01:21
User entered '1 Feb 2021'	Monique Gawlik (b) (4)	04 Feb 2021 16:05:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:18

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:01:21
User entered empty.	Monique Gawlik (b) (4)	04 Feb 2021 16:05:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:18

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 16:05:45

US3912163
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 10:19:18
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:57:57
DataPoint Un-verified.	Sandra Clancy (b) (4)	10 Feb 2021 16:19:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Sandra Clancy (b) (4)	10 Feb 2021 16:19:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:01:21
User entered 'Yes (Y)'	Monique Gawlik (b) (4)	04 Feb 2021 16:05:45

US3912163

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:18

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:58:01
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	10 Feb 2021 16:19:24
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	10 Feb 2021 16:19:24
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	10 Feb 2021 16:19:04
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:19:04
User entered '2 Feb 2021' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:19:04
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:01:21
User entered empty.	Monique Gawlik (b) (4)	04 Feb 2021 16:05:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:18

End time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:01:21
User entered empty.	Monique Gawlik (b) (4)	04 Feb 2021 16:05:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:18

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 16:05:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:18

Severity

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:01:21
User entered 'Grade 3/Severe (Grade 3/Severe)'	Monique Gawlik (b) (4)	04 Feb 2021 16:05:45

US3912163
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 10:19:18
Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:01:21
User entered 'Yes (Y)'	Monique Gawlik (b) (4)	04 Feb 2021 16:05:45

US3912163
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 10:19:18
Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:01:09
User entered '0'	Monique Gawlik (b) (4)	04 Feb 2021 16:05:45

US3912163

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:18

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:01:08
User entered '1'	Monique Gawlik (b) (4)	04 Feb 2021 16:05:45

US3912163

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:18

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:01:06
User entered '1'	Monique Gawlik (b) (4)	04 Feb 2021 16:05:45

US3912163
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 10:19:18
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:01:05
User entered '1 Feb 2021'	Monique Gawlik (b) (4)	04 Feb 2021 16:05:45

US3912163
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 10:19:18
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:58:07
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:19:04
User entered '2 Feb 2021' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:19:04
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:01:03
User entered '3 Feb 2021'	Monique Gawlik (b) (4)	04 Feb 2021 16:05:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:18

Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:09:34
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	05 Feb 2021 21:38:13
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).	System	05 Feb 2021 21:38:13
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	05 Feb 2021 21:38:13
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Feb 2021 21:38:13
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:01:02
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	04 Feb 2021 16:05:45
User entered 'Unknown (UNK)'	Monique Gawlik (b) (4)	04 Feb 2021 16:05:45

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:01:21
User entered empty.	Monique Gawlik (b) (4)	04 Feb 2021 16:05:45

US3912163

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:18

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:01:21
User entered '0'	Monique Gawlik (b) (4)	04 Feb 2021 16:05:45

US3912163

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:18

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:01:21
User entered '0'	Monique Gawlik (b) (4)	04 Feb 2021 16:05:45

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:01:21
User entered '0'	Monique Gawlik (b) (4)	04 Feb 2021 16:05:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:18

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:01:21
User entered 'Not Related (NOT RELATED)'	Monique Gawlik (b) (4)	04 Feb 2021 16:05:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:18

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:01:21
User entered 'Not Related (NOT RELATED)'	Monique Gawlik (b) (4)	04 Feb 2021 16:05:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:18

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:59:08
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Feb 2021 21:39:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Feb 2021 21:39:11
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	05 Feb 2021 21:39:11
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Feb 2021 21:39:11
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:01:21
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Feb 2021 16:05:45
User entered empty.	Monique Gawlik (b) (4)	04 Feb 2021 16:05:45

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US3912163
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 10:19:18
None

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:01:21
User entered '0'	Monique Gawlik (b) (4)	04 Feb 2021 16:05:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:18

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:01:21
User entered '1'	Monique Gawlik (b) (4)	04 Feb 2021 16:05:45

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:18

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:01:21
User entered '1'	Monique Gawlik (b) (4)	04 Feb 2021 16:05:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:18

Outcome

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User closed query 'Per source document, MI is still 'recovering/resolving'. Please update EDC or source. ' (Site from CRA).	(b) (4), (b) (6)	11 Mar 2021 17:41:41
Query 'Per source document, MI is still 'recovering/resolving'. Please update EDC or source. ' answered with 'source was update 10Feb2021 with 'recovered'' (Site from CRA).	Sandra Clancy (b) (4) (b) (4)	10 Mar 2021 20:12:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:01
User opened query 'Per source document, MI is still 'recovering/resolving'. Please update EDC or source. ' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 15:58:59
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:19:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:19:24
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:01:21
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Monique Gawlik (b) (4)	04 Feb 2021 16:05:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:18

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:01:21
User entered empty.	Monique Gawlik (b) (4)	04 Feb 2021 16:05:45

US3912163

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:18

Narrative

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:03
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 11:48:04
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 14:07:47
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 14:07:37
User closed query 'PV Query: Please provide dates for angioplasty and stent placement. ' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 14:07:31
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'records sent today' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 21:16:41
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' answered with 'no covid testing according to medical records' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 20:45:09

Audit	User		Time (GMT)
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' answered with 'significant medical history of hypertension, tobacco abuse and strong family history of cardiovascular disease.' (Site from Safety).	Sandra Clancy	(b) (4) (b) (4)	11 Feb 2021 20:44:38
User entered 'SUBJECT UNDERWENT ANGIOPLASTY AND STENT PLACEMENT on 01Feb2021.	Sandra Clancy	(b) (4) (b) (4)	11 Feb 2021 20:40:17
SUBJECT EXPERIENCED NEW ONSET OF CHEST PAIN THE MORNING OF 01FEB2021; HE PRESENTED TO FREE STANDING ER FOR EVALUATION AND DUE TO NOTED INCREASE IN CARDIAC ENZYMES HE WAS TRANSFERRED TO ER WITH HIGHER LEVEL OF CARE. UPON PRESENTATION TO 2ND ER, HE WAS TAKEN EMERGENTLY TO THE CATH LAB WHERE HE UNDERWENT CARDIAC CATHETERIZATION. THAT PROCEDURE REVEALED SIGNIFICANT CORONARY ARTERY DISEASE OF THE LEFT CIRCUMFLEX (70% STENOSIS) WITH APPEARANCE OF ULCERATED PLAQUE; SUCCESSFUL PCI OF THE MID LEFT CIRCUMFLEX ARTERY USING 2.25 X 22MM RESOLUTE ONXY DRUG ELUDING STENT WITH IMPROVEMENT IN STENOSIS SEVERITY FROM 70% WITH ULCERATED PLAQUE TO 0% RESIDUAL STENOSIS AND TIMI 3 FLOW POST INTERVENTION.' reason for change: Data Entry Error			
Query 'PV Query: Please provide dates for angioplasty and stent placement. ' answered with 'both angioplasty and stent placement were performed on 01Feb2021.' (Site from Safety).	Sandra Clancy	(b) (4) (b) (4)	11 Feb 2021 20:39:38

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 20:12:36
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 20:12:19
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 20:11:04
User opened query 'PV Query: Please provide dates for angioplasty and stent placement. ' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 20:10:49
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:30:02
User entered 'SUBJECT UNDERWENT ANGIOPLASTY AND STENT PLACEMENT. Subject experienced new onset of chest pain the morning of 01Feb2021; he presented to free standing ER for evaluation and due to noted increase in cardiac enzymes he was transferred to ER with higher level of care. Upon presentation to 2nd ER, he was taken emergently to the cath lab where he underwent cardiac catheterization. That procedure revealed significant coronary artery disease of the left circumflex (70% stenosis) with appearance of ulcerated plaque; successful PCI of the mid left circumflex artery using 2.25 x 22mm Resolute Onxy drug eluding stent with improvement in stenosis severity from 70% with ulcerated plaque to 0% residual stenosis and TIMI 3 flow post intervention.' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:30:02
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:01:21

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:18

Narrative

Audit	User	Time (GMT)
User entered 'Subject underwent angioplasty and stent placement.'	Monique Gawlik (b) (4)	04 Feb 2021 16:05:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:18

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 16:05:45

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 16:05:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:19:18

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	04 Feb 2021 16:05:45

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Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 10:19:18

Adverse event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:46:26
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Feb 2021 16:52:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Feb 2021 16:52:48
Data point term sent to Coder	System	10 Feb 2021 16:51:39
User entered 'hyperlipidemia'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:51:35

US3912163
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 10:19:18
Was this a medically-attended AE?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:46:26
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:51:35

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:19:18

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:46:26
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:51:35

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Folder: Adverse Events

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Generated On: 10 Jun 2021 10:19:18

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:46:26
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:51:35

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:19:18

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:46:26
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User entered '1 Feb 2021'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:51:35

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:46:26
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User entered empty.	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:51:35

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:19:18

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 16:51:35

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:19:18

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:46:26
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:51:35

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:19:18

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:46:26
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User entered empty.	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:51:35

Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 10:19:18

End time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:46:26
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User entered empty.	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:51:35

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:19:18

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 16:51:35

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:19:18

Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:46:26
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:51:35

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:19:18

Is the adverse event serious?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:46:26
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:51:35

US3912163
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 10:19:18
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:46:26
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User entered '0'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:51:35

US3912163

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:19:18

Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:46:26
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User entered '0'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:51:35

US3912163

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:19:18

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:46:26
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User entered '0'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:51:35

US3912163

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:19:18

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:46:26
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User entered empty.	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:51:35

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:19:18

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:46:26
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User entered empty.	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:51:35

US3912163

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:19:18

Admitted to ICU?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:46:26
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User entered empty.	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:51:35

Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:46:26
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User entered empty.	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:51:35

FDA-CBER-2022-1614-3510697

US3912163

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:19:18

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:46:26
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User entered '0'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:51:35

US3912163

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:19:18

Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:46:26
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User entered '0'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:51:35

US3912163

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:19:18

Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:46:26
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User entered '0'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:51:35

US3912163

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:19:18

Relationship to investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:46:26
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Feb 2021 20:49:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Feb 2021 20:49:10
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 20:49:10
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 16:51:35
User entered empty.	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:51:35

US3912163

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:19:18

Relationship to Study Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:46:26
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Feb 2021 20:49:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Feb 2021 20:49:10
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 20:49:10
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 16:51:35
User entered empty.	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:51:35

US3912163

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:19:18

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:46:26
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Feb 2021 20:49:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Feb 2021 20:49:10
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 20:49:10
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 16:51:35
User entered empty.	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:51:35

FDA-CBER-2022-1614-3510703

US3912163
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 10:19:18
None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:46:26
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User entered '0'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:51:35

US3912163

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:19:18

Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:46:26
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User entered '1'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:51:35

US3912163

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:19:18

Concomitant Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:46:26
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User entered '0'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:51:35

US3912163

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:19:18

Outcome

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:46:26
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:51:35

US3912163

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:19:18

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:46:26
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User entered empty.	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:51:35

US3912163
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 10:19:18
Narrative

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:46:26
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User entered empty.	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:51:35

US3912163

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:19:18

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	10 Feb 2021 16:51:35

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	10 Feb 2021 16:51:35

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:19:18

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:00:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:01
User closed query 'Per ETRTR: According to AE page, medication was dosed for COVID-19. Please add Medication dosing details as required, thanks.' (Site from CRA).	(b) (4), (b) (6)	13 Jan 2021 20:39:20
Query 'Per ETRTR: According to AE page, medication was dosed for COVID-19. Please add Medication dosing details as required, thanks.' answered with 'con meds updated' (Site from CRA).	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:53:15
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:54:50
User opened query 'Per ETRTR: According to AE page, medication was dosed for COVID-19. Please add Medication dosing details as required, thanks.' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 17:54:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 13:55:03

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:18

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:11
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL TARTRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 13:57:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 13:57:46
Data point term sent to Coder	System	22 Sep 2020 13:56:40
User entered 'metoprolol tartrate'	(b) (4), (b) (6)	22 Sep 2020 13:55:58

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:18

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:11
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 13:55:58

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:18

Indication

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:11
User entered 'hypertension'	(b) (4), (b) (6)	22 Sep 2020 13:55:58

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:18

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:11
User entered '50'	(b) (4), (b) (6)	22 Sep 2020 13:55:58

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:18

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:11
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Sep 2020 13:55:58

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:11
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 13:55:58

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:18

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:11
User entered 'once daily (QD)'	(b) (4), (b) (6)	22 Sep 2020 13:55:58

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:18

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:11
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 13:55:58

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:18

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:11
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Sep 2020 13:55:58

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:11
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 13:55:58

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:18

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:24:11
User entered 'un Sep 2018'	(b) (4), (b) (6)	22 Sep 2020 13:55:58

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:18

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:11
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 13:55:58

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:18

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:24:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 13:55:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:18

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:24:11
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 13:55:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:18

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:11
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 13:55:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:18

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 13:55:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:19:18

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 13:55:58

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 13:55:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:34
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:11
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: INTESTINAL ADSORBENTS, ATC: BISMUTH PREPARATIONS, PRODUCT: BISMUTH SUBSALICYLATE, PRODUCTSYNONYM: PEPTO-BISMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 18:00:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 18:00:43
Data point term sent to Coder	System	22 Dec 2020 19:44:08
User entered 'pepto bismol for diarrhea'	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 19:43:54

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:18

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:34
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:11
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 19:43:54

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:18

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:34
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 09:50:20
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'subject diagnosed with symptomatic Covid and AE prepared. This is one of active symptoms experienced during this episode.' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:16:19
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:11
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 07:39:02
User entered 'diarrhea'	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 19:43:54

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:18

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:34
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
User closed query 'Per DM CLR: Please provide the dose in MG for this medication instead of ML as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 14:51:12
Query 'Per DM CLR: Please provide the dose in MG for this medication instead of ML as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'the dose and dose unit is taken directly from the bottle as reported by the subject.' (Site from DM).	Sandra Clancy (b) (4)	10 Mar 2021 20:15:25
User opened query 'Per DM CLR: Please provide the dose in MG for this medication instead of ML as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Mar 2021 09:52:49
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:11
User entered '60'	Sandra Clancy (b) (4)	22 Dec 2020 19:43:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:18

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:34
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:11
User entered 'mL (mL)'	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 19:43:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:34
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:11
User entered empty.	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 19:43:54

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:18

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:34
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:11
User entered 'once (ONCE)'	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 19:43:54

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:34
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:11
User entered empty.	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 19:43:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:18

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:34
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:11
User entered 'Oral (ORAL)'	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 19:43:54

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:34
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:11
User entered empty.	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 19:43:54

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:18

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:34
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:11
User entered '16 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 19:43:54

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:18

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:34
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:11
User entered '0'	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 19:43:54

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:18

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:34
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:11
User entered 'No (N)'	Sandra Clancy (b) (4)	22 Dec 2020 19:43:54

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:18

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:34
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:11
User entered '16 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 19:43:54

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:18

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:34
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:44:33
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, conmed was used after 7 days post vaccination and conmed indication indicates this is an Unsolicited event. Review if this should be updated to No. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 09:50:41
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, conmed was used after 7 days post vaccination and conmed indication indicates this is an Unsolicited event. Review if this should be updated to No. Else, clarify.' answered with 'corrected' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:49:54
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:49:44
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:49:44
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:11
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, conmed was used after 7 days post vaccination and conmed indication indicates this is an Unsolicited event. Review if this should be updated to No. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 07:39:12
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 19:43:54

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:18

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:34
User entered empty.	System	22 Dec 2020 19:43:54

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:18

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:34
User entered empty.	System	22 Dec 2020 19:43:54

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:19:18

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:34
User entered empty.	System	22 Dec 2020 19:43:54

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:40
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User closed query 'Per source documentation, subject started aspirin 81 mg on 07Dec2020 and use is ongoing. Please add to EDC or clarify, Thank you!' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 22:55:30
Query 'Per source documentation, subject started aspirin 81 mg on 07Dec2020 and use is ongoing. Please add to EDC or clarify, Thank you!' answered with 'clarified' (Site from CRA).	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:21:42
User opened query 'Per source documentation, subject started aspirin 81 mg on 07Dec2020 and use is ongoing. Please add to EDC or clarify, Thank you!' (Site from CRA).	(b) (4), (b) (6)	20 Jan 2021 22:45:20
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:43:50
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 23:32:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 23:32:49
Data point term sent to Coder	System	11 Jan 2021 23:31:37
User entered 'ibuprofen'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:31:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:18

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:40
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:43:50
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:31:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:18

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:40
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 22:43:50
User entered 'body aches'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:31:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:18

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:40
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:43:50
User entered '200'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:31:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:18

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:40
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:43:50
User entered 'mg (mg)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:31:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:40
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:43:50
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:31:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:18

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:40
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:43:50
User entered 'as needed (PRN)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:31:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:40
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:43:50
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:31:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:18

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:40
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:43:50
User entered 'Oral (ORAL)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:31:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:40
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:43:50
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:31:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:18

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:40
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:43:50
User entered '7 Dec 2020'	Sandra Clancy (b) (4)	11 Jan 2021 23:31:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:18

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:40
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:43:50
User entered '0'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:31:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:18

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:40
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:43:50
User entered 'No (N)'	Sandra Clancy (b) (4)	11 Jan 2021 23:31:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:18

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:40
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:43:50
User entered '21 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:31:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:18

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:40
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:44:36
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not within the 7 day post IP admin. Update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 07:11:42
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not within the 7 day post IP admin. Update as appropriate. Otherwise, provide clarification. ' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	10 Mar 2021 20:16:10
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	10 Mar 2021 20:16:02
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	10 Mar 2021 20:16:02
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not within the 7 day post IP admin. Update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:34:04
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:43:50
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:31:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:18

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:40
User entered empty.	System	11 Jan 2021 23:31:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:18

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:40
User entered empty.	System	11 Jan 2021 23:31:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:19:18

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:40
User entered empty.	System	11 Jan 2021 23:31:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL, PRODUCTSYNONYM: NYQUIL COLD & FLU - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 13:06:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 13:06:03
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:43:54
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: OTHER COLD PREPARATIONS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL, PRODUCTSYNONYM: NYQUIL COLD & FLU - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Jan 2021 15:50:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Jan 2021 15:50:05
Data point term sent to Coder	System	11 Jan 2021 23:37:38
User entered 'nyquil cold & flu'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:37:26

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:18

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:34
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:43:54
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:37:26

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:18

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:34
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:43:54
User entered 'nasal congestion'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:37:26

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:18

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:34
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:43:54
User entered '30'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:37:26

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:18

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:34
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:43:54
User entered 'mL (mL)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:37:26

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:34
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:43:54
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:37:26

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:18

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:34
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:43:54
User entered 'as needed (PRN)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:37:26

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:34
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:43:54
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:37:26

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:18

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:34
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:43:54
User entered 'Oral (ORAL)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:37:26

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:34
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:43:54
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:37:26

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:18

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:34
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:43:54
User entered '7 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:37:26

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:18

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:34
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:43:54
User entered '0'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:37:26

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:18

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:34
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:43:54
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:37:26

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:18

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:34
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:43:54
User entered '21 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:37:26

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:18

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:34
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:44:45
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not within the 7 day post IP admin. Update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 07:11:54
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not within the 7 day post IP admin. Update as appropriate. Otherwise, provide clarification. ' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	10 Mar 2021 20:16:33
DataPoint Un-verified.	Sandra Clancy (b) (4)	10 Mar 2021 20:16:26
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	10 Mar 2021 20:16:26
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not within the 7 day post IP admin. Update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:34:33
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:43:54
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:37:26

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:34
User entered empty.	System	11 Jan 2021 23:37:26

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:18

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:34
User entered empty.	System	11 Jan 2021 23:37:26

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:19:18

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:06:34
User entered empty.	System	11 Jan 2021 23:37:26

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:49
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:44:01
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 23:40:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 23:40:52
Data point term sent to Coder	System	11 Jan 2021 23:39:38
User entered 'guaifenesin'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:38:44

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:18

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:49
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:44:01
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:38:44

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:18

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:49
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:44:01
User entered 'cough'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:38:44

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:18

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:49
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:44:01
User entered '400'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:38:44

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:18

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:49
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:44:01
User entered 'mg (mg)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:38:44

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:49
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:44:01
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:38:44

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:18

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:49
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:44:01
User entered 'as needed (PRN)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:38:44

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:49
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:44:01
User entered empty.	Sandra Clancy (b) (4)	11 Jan 2021 23:38:44

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:18

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:49
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:44:01
User entered 'Oral (ORAL)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:38:44

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:49
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:44:01
User entered empty.	Sandra Clancy (b) (4)	11 Jan 2021 23:38:44
	(b) (4)	

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:18

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:49
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:44:01
User entered '7 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:38:44

FDA-CBER-2022-1614-3510795

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:18

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:49
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:44:01
User entered '0'	Sandra Clancy (b) (4)	11 Jan 2021 23:38:44

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:18

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:49
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:44:01
User entered 'No (N)'	Sandra Clancy (b) (4)	11 Jan 2021 23:38:44
	(b) (4)	

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:18

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:49
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:44:01
User entered '10 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:38:44

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:18

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:44:49
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not within the 7 day post IP admin. Update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 07:12:07
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not within the 7 day post IP admin. Update as appropriate. Otherwise, provide clarification. ' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	10 Mar 2021 20:16:52
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	10 Mar 2021 20:16:46
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	10 Mar 2021 20:16:46
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not within the 7 day post IP admin. Update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:35:02
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:44:01
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:38:44

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:18

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:49
User entered empty.	System	11 Jan 2021 23:38:44

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:49
User entered empty.	System	11 Jan 2021 23:38:44

FDA-CBER-2022-1614-3510801

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:19:18

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:40:49
User entered empty.	System	11 Jan 2021 23:38:44

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:01
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:44:03
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: ANTIALLERGIC AGENTS, EXCL. CORTICOSTEROIDS, PRODUCT: AZELASTINE HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Jan 2021 14:59:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Jan 2021 14:59:54
Data point term sent to Coder	System	11 Jan 2021 23:40:39
User entered 'azelastine HCl nasal solution'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:39:59

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:18

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:01
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:44:03
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:39:59

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:18

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:01
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:44:03
User entered 'nasal congestion'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:39:59

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:18

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:01
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:44:03
User entered '137'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:39:59

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:18

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:01
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:44:03
User entered 'ug (ug)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:39:59

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:01
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:44:03
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:39:59

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:18

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:01
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:44:03
User entered 'twice daily (BID)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:39:59

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:01
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:44:03
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:39:59

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:18

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:01
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:44:03
User entered 'Nasal (NASAL)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:39:59

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:01
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:44:03
User entered empty.	Sandra Clancy (b) (4)	11 Jan 2021 23:39:59
	(b) (4)	

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:18

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:01
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:44:03
User entered '7 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:39:59

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:18

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:01
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:44:03
User entered '0'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:39:59

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:18

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:01
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:44:03
User entered 'No (N)'	Sandra Clancy (b) (4)	11 Jan 2021 23:39:59
	(b) (4)	

FDA-CBER-2022-1614-3510815

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:18

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:01
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:44:03
User entered '21 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:39:59

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:18

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:01
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:44:54
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not within the 7 day post IP admin. Update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 07:12:20
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not within the 7 day post IP admin. Update as appropriate. Otherwise, provide clarification. ' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	10 Mar 2021 20:17:20
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	10 Mar 2021 20:17:06
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	10 Mar 2021 20:17:06
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not within the 7 day post IP admin. Update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:35:26
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:44:03
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:39:59

FDA-CBER-2022-1614-3510817

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:18

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:01
User entered '2'	System	11 Jan 2021 23:39:59

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:18

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:01
User entered '1'	System	11 Jan 2021 23:39:59

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:19:18

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:01
User entered '804 (804)'	System	11 Jan 2021 23:39:59

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:18

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:30
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 23:42:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 23:42:44
Data point term sent to Coder	System	11 Jan 2021 23:41:40
User entered 'zinc'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:40:48

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:18

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:30
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:40:48

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:18

Indication

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:30
User entered 'health supplement'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:40:48

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:18

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:30
User entered '250'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:40:48

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:18

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:30
User entered 'mg (mg)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:40:48

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:30
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:40:48

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:18

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:30
User entered 'twice daily (BID)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:40:48

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:18

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:30
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:40:48

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:18

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:30
User entered 'Oral (ORAL)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:40:48

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:30
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:40:48

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:18

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:30
User entered '7 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:40:48

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:18

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:30
User entered '0'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:40:48

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:18

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:30
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:40:48

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:18

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:30
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:40:48

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:18

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:30
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:40:48

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:18

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	11 Jan 2021 23:40:48

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:18

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Jan 2021 23:40:48

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:19:18

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Jan 2021 23:40:48

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:19:18

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 23:43:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 23:43:43
Data point term sent to Coder	System	11 Jan 2021 23:42:41
User entered 'vitamin C'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:41:48

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:19:18

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:34
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:41:48

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:19:18

Indication

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:34
User entered 'health supplement'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:41:48

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:19:18

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:34
User entered '1000'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:41:48

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:19:18

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:34
User entered 'mg (mg)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:41:48

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:19:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:34
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:41:48

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:19:18

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:34
User entered 'twice daily (BID)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:41:48

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:19:18

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:34
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:41:48

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:19:18

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:34
User entered 'Oral (ORAL)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:41:48

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:19:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:34
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:41:48

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:19:18

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:34
User entered '7 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:41:48

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:19:18

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:34
User entered '0'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:41:48

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:19:18

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:34
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:41:48

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:19:18

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:34
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:41:48

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:19:18

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:34
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:41:48

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:19:18

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	11 Jan 2021 23:41:48

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:19:18

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Jan 2021 23:41:48

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:19:18
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Jan 2021 23:41:48

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:15
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 22:45:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE, PRODUCTSYNONYM: TYLENOL COLD & FLU SEVERE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Jan 2021 16:13:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Jan 2021 16:13:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: CHLORPHENAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: TYLENOL COLD & FLU - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 23:47:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 23:47:55
Data point term sent to Coder	System	11 Jan 2021 23:47:53
User entered 'TYLENOL COLD & FLU (acetaminophen 325 mg; dextromethorphan 10 mg; guaifenesin 200 mg; phenylephrine HCI 5 mg)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:47:33
Data point term sent to Coder	System	11 Jan 2021 23:46:42
User entered 'tylenol cold & flu'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:46:26

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:18

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:15
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:37
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:46:26

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:18

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:15
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:37
User entered 'nasal congestion'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:46:26

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:18

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:15
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:37
User entered '1'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:46:26

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:18

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:15
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:37
User entered 'capsule (CAPSULE)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:46:26

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:15
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:37
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:46:26

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:18

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:15
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:37
User entered 'twice daily (BID)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:46:26

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:15
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:37
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:46:26

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:18

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:15
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:37
User entered 'Oral (ORAL)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:46:26

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:15
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:37
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:46:26

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:18

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:15
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:37
User entered '7 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:46:26

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:18

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:15
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:37
User entered '0'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:46:26

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:18

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:15
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:37
User entered 'No (N)'	Sandra Clancy (b) (4)	11 Jan 2021 23:46:26

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:18

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:15
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:37
User entered '8 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:46:26

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:18

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:15
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:45:04
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not within the 7 day post IP admin. Update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 07:12:36
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not within the 7 day post IP admin. Update as appropriate. Otherwise, provide clarification. ' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	10 Mar 2021 20:17:42
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	10 Mar 2021 20:17:35
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	10 Mar 2021 20:17:35
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not within the 7 day post IP admin. Update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:35:44
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:37
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:46:26

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:18

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:15
User entered '2'	System	11 Jan 2021 23:46:26

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:18

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:15
User entered '1'	System	11 Jan 2021 23:46:26

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:19:18

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:41:15
User entered '804 (804)'	System	11 Jan 2021 23:46:26

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:18

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
Query 'Queries cannot be placed on log lines or eCRF pages that do not have subject data already entered by site staff, therefore query placement will remain as is. Please add data to EDC, as applicable. Thank you!' canceled (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 18:38:50
User opened query 'Queries cannot be placed on log lines or eCRF pages that do not have subject data already entered by site staff, therefore query placement will remain as is. Please add data to EDC, as applicable. Thank you!' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 18:38:14
User closed query 'Per source documentation, subject started 60 mL Pepto-Bismol use from 16-Dec-2020 to 16-Dec-2020. Please add to EDC or clarify. Thank you!' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 18:38:14
Query 'Per source documentation, subject started 60 mL Pepto-Bismol use from 16-Dec-2020 to 16-Dec-2020. Please add to EDC or clarify. Thank you!' answered with 'please place query on the appropriate eCRF entry - thanks' (Site from CRA).	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:49:22
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:24
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:16
User opened query 'Per source documentation, subject started 60 mL Pepto-Bismol use from 16-Dec-2020 to 16-Dec-2020. Please add to EDC or clarify. Thank you!' (Site from CRA).	(b) (4), (b) (6)	20 Jan 2021 22:46:53
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS, PRODUCT: CALCIUM;MAGNESIUM;ZINC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Jan 2021 15:31:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Jan 2021 15:31:54
Data point term sent to Coder	System	11 Jan 2021 23:49:54

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US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:18

Name of Medication

Audit	User	Time (GMT)
User entered 'Mineral supplement (calcium, magnesium, and zinc)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:49:05

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:18

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:24
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:16
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:47
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:49:05

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:18

Indication

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:24
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:16
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:47
User entered 'health supplement'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:49:05

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:18

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:24
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:16
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:47
User entered '1'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:49:05

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:18

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:24
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:16
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:47
User entered 'tablet (TABLET)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:49:05

FDA-CBER-2022-1614-3510880

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:24
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:16
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:47
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:49:05

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:18

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:24
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:16
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:47
User entered 'twice daily (BID)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:49:05

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:18

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:24
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:16
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:47
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:49:05

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:18

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:24
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:16
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:47
User entered 'Oral (ORAL)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:49:05

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:24
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:16
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:47
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:49:05

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:18

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:24
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:16
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:47
User entered '7 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:49:05

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:18

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:24
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:16
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:47
User entered '0'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:49:05

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:18

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:24
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:16
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:47
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:49:05

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:18

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:24
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:16
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:47
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:49:05

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:18

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:24
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 19:24:16
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:47
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 23:49:05

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:18

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	11 Jan 2021 23:49:05

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:18

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Jan 2021 23:49:05

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:19:18

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Jan 2021 23:49:05

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:18

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:45:16
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:48
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 16:50:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 16:50:48
Data point term sent to Coder	System	10 Feb 2021 16:50:39
Coding entries removed.	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:50:33
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Feb 2021 18:04:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Feb 2021 18:04:34
Data point term sent to Coder	System	08 Feb 2021 18:03:47
User entered 'rosuvastatin'	Tina Rountree (b) (4) (b) (4)	08 Feb 2021 18:03:18

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:18

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:45:19
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:48
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	08 Feb 2021 18:03:18

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:18

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:45:22
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:48
User entered 'HYPERlipidemia' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	10 Feb 2021 16:50:33
User entered 'hypertension'	Tina Rountree (b) (4) (b) (4)	08 Feb 2021 18:03:18

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:18

Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:45:23
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:48
User entered '20'	Tina Rountree (b) (4) (b) (4)	08 Feb 2021 18:03:18

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:18

Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:45:25
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:14:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:48
User entered 'mg (mg)'	Tina Rountree (b) (4) (b) (4)	08 Feb 2021 18:03:18

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:18

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:45:27
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:14:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:48
User entered empty.	Tina Rountree (b) (4) (b) (4)	08 Feb 2021 18:03:18

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:18

Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:45:29
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:48
User entered 'twice daily (BID)'	Tina Rountree (b) (4) (b) (4)	08 Feb 2021 18:03:18

FDA-CBER-2022-1614-3510900

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:18

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:45:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:48
User entered empty.	Tina Rountree (b) (4) (b) (4)	08 Feb 2021 18:03:18

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:18

Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:45:31
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:48
User entered 'Oral (ORAL)'	Tina Rountree (b) (4) (b) (4)	08 Feb 2021 18:03:18

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:18

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:45:33
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:48
User entered empty.	Tina Rountree (b) (4) (b) (4)	08 Feb 2021 18:03:18

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:18

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:45:34
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:14:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:48
User entered '1 Feb 2021'	Tina Rountree (b) (4) (b) (4)	08 Feb 2021 18:03:18

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:18

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:45:36
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:14:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:48
User entered '0'	Tina Rountree (b) (4) (b) (4)	08 Feb 2021 18:03:18

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:18

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:45:38
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:48
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	08 Feb 2021 18:03:18

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:18

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:45:39
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:48
User entered empty.	Tina Rountree (b) (4) (b) (4)	08 Feb 2021 18:03:18

FDA-CBER-2022-1614-3510907

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:18

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:45:40
User signature succeeded.	Mark Hutchens (b) (4)	11 Mar 2021 17:48:52
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:48
User entered 'No (N)'	Tina Rountree (b) (4)	08 Feb 2021 18:03:18

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:18

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	08 Feb 2021 18:03:18

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:19:18

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	08 Feb 2021 18:03:18

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 10:19:18
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Feb 2021 18:03:18

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:18

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:13:54
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 18:23:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 18:23:55
Data point term sent to Coder	System	11 Feb 2021 18:23:39
User entered 'aspirin'	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:23:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:18

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:13:54
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:23:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:18

Indication

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:13:54
User entered 'myocardial infarction'	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:23:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:18

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:13:54
User entered '81'	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:23:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:18

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:13:54
User entered 'mg (mg)'	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:23:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:13:54
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:23:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:18

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:13:54
User entered 'once daily (QD)'	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:23:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:18

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:13:54
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:23:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:18

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:13:54
User entered 'Oral (ORAL)'	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:23:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:13:54
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:23:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:18

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:13:54
User entered '1 Feb 2021'	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:23:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:18

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:13:54
User entered '0'	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:23:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:18

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:13:54
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:23:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:18

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:13:54
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:23:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:18

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:13:54
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:23:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:18

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Feb 2021 18:23:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:18

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Feb 2021 18:23:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:19:18

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Feb 2021 18:23:09

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:19:18

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:13:59
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: TICAGRELOR, PRODUCTSYNONYM: BRILINTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 18:24:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 18:24:54
Data point term sent to Coder	System	11 Feb 2021 18:24:39
User entered 'brilinta'	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:24:08

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 10:19:18

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:13:59
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:24:08

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:19:18

Indication

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:13:59
User entered 'Myocardial infarction'	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:24:08

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:19:18

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:13:59
User entered '90'	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:24:08

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:19:18

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:13:59
User entered 'mg (mg)'	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:24:08

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:19:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:13:59
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:24:08

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:19:18

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:13:59
User entered 'twice daily (BID)'	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:24:08

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:19:18

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:13:59
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:24:08

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:19:18

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:13:59
User entered 'Oral (ORAL)'	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:24:08

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:19:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:13:59
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:24:08

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:19:18

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:13:59
User entered '1 Feb 2021'	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:24:08

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:19:18

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:13:59
User entered '0'	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:24:08

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:19:18

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:13:59
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:24:08

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:19:18

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:13:59
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:24:08

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:19:18

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:13:59
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:24:08

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	11 Feb 2021 18:24:08

FDA-CBER-2022-1614-3510945

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:19:18

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Feb 2021 18:24:08

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:19:18

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Feb 2021 18:24:08

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:18

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:04
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Feb 2021 21:51:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Feb 2021 21:51:44
Data point term sent to Coder	System	11 Feb 2021 18:27:47
User entered 'nitroglycerin'	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:26:59

FDA-CBER-2022-1614-3510948

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:18

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:04
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:26:59

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:18

Indication

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:04
User entered 'myocardial infarction'	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:26:59

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:18

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:04
User entered '0.4'	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:26:59

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:18

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:04
User entered 'mg (mg)'	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:26:59

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:04
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:26:59

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:18

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:04
User entered 'as needed (PRN)'	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:26:59

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:18

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:04
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:26:59

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:18

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:04
User entered 'Other (OTHER)'	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:26:59

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:04
User entered 'sublingual'	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:26:59

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:18

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:04
User entered '1 Feb 2021'	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:26:59

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:18

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:04
User entered '0'	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:26:59

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:18

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:04
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:26:59

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:18

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:04
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:26:59

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:18

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	11 Mar 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:14:04
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	11 Feb 2021 18:26:59

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:18

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 18:26:59

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:18

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 18:26:59

US3912163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:19:18

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 18:26:59

US3912163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:19:18

Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:00:57
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:01:56
User entered 'Yes (Y)'	Monique Gawlik (b) (4)	04 Feb 2021 16:06:02

US3912163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:19:18

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:02:04
User entered '1 Feb 2021'	Monique Gawlik (b) (4)	04 Feb 2021 16:06:38

US3912163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:19:18

Procedure/Surgery

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:02:04
User entered 'stent placement'	Monique Gawlik (b) (4)	04 Feb 2021 16:06:38

US3912163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:19:18

Indication

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:02:04
User entered 'Adverse Event (AE)'	Monique Gawlik (b) (4)	04 Feb 2021 16:06:38

US3912163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:19:18

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:02:04
User entered empty.	Monique Gawlik (b) (4)	04 Feb 2021 16:06:38

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:27
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:02:04
User entered '1 Feb 2021'	Monique Gawlik (b) (4)	04 Feb 2021 16:07:04

US3912163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:19:18

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:27
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:02:04
User entered 'angioplasty'	Monique Gawlik (b) (4)	04 Feb 2021 16:07:04

US3912163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:19:18

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:27
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:02:04
User entered 'Adverse Event (AE)'	Monique Gawlik (b) (4)	04 Feb 2021 16:07:04

US3912163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:19:18

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:27
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:02:04
User entered empty.	Monique Gawlik (b) (4)	04 Feb 2021 16:07:04

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'USA-US211-2020-MRNA-1273-P301000008'	System	17 Dec 2020 18:14:10

US3912163

Folder: SAE USA-US211-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'No (N)'	System	17 Dec 2020 18:14:10

Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'No (N)'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'No (N)'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'No (N)'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'No (N)'	System	17 Dec 2020 18:14:10

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'No (N)'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'No (N)'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18

Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:43:35
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	12 Mar 2021 19:13:20
Un-reviewed for Safety.	System	11 Mar 2021 21:47:53
DataPoint Un-verified.	System	11 Mar 2021 21:47:53
Signature has been broken.	System	11 Mar 2021 21:47:53
User entered 'Mark'	System	11 Mar 2021 21:47:53
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Un-reviewed for Safety.	System	23 Dec 2020 13:55:24
User entered 'Timothy'	System	23 Dec 2020 13:55:24
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'Mohammad'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18

Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:43:37
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	12 Mar 2021 19:13:20
Un-reviewed for Safety.	System	11 Mar 2021 21:47:53
DataPoint Un-verified.	System	11 Mar 2021 21:47:53
Signature has been broken.	System	11 Mar 2021 21:47:53
User entered 'Hutchens'	System	11 Mar 2021 21:47:53
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Un-reviewed for Safety.	System	23 Dec 2020 13:55:24
User entered 'Vachris'	System	23 Dec 2020 13:55:24
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'Naqvi'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Un-reviewed for Safety.	System	23 Dec 2020 13:55:24
User entered empty.	System	23 Dec 2020 13:55:24
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'NY'	System	17 Dec 2020 18:14:10

FDA-CBER-2022-1614-3510985

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 13:55:09
User entered 'US'	System	17 Dec 2020 18:15:26

US3912163

Folder: SAE USA-US211-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:18

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '4'	System	11 Mar 2021 21:47:53
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '3'	System	11 Jan 2021 19:53:00
User entered '2'	System	23 Dec 2020 13:55:24
User entered '1'	System	17 Dec 2020 18:15:26

US3912163

Folder: SAE USA-US211-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:18

SAEID

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'USA-US211-2020-MRNA-1273-P301000008'	System	17 Dec 2020 18:14:10

Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'No (N)'	System	17 Dec 2020 18:14:10

Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'No (N)'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'No (N)'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'No (N)'	System	17 Dec 2020 18:14:10

US3912163

Folder: SAE USA-US211-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:18

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'No (N)'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'No (N)'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'No (N)'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:43:35
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	12 Mar 2021 19:13:20
Un-reviewed for Safety.	System	11 Mar 2021 21:47:53
DataPoint Un-verified.	System	11 Mar 2021 21:47:53
Signature has been broken.	System	11 Mar 2021 21:47:53
User entered 'Mark'	System	11 Mar 2021 21:47:53
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Un-reviewed for Safety.	System	23 Dec 2020 13:55:24
User entered 'Timothy'	System	23 Dec 2020 13:55:24
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'Mohammad'	System	17 Dec 2020 18:14:10

Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:43:37
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	12 Mar 2021 19:13:20
Un-reviewed for Safety.	System	11 Mar 2021 21:47:53
DataPoint Un-verified.	System	11 Mar 2021 21:47:53
Signature has been broken.	System	11 Mar 2021 21:47:53
User entered 'Hutchens'	System	11 Mar 2021 21:47:53
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Un-reviewed for Safety.	System	23 Dec 2020 13:55:24
User entered 'Vachris'	System	23 Dec 2020 13:55:24
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'Naqvi'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Un-reviewed for Safety.	System	23 Dec 2020 13:55:24
User entered empty.	System	23 Dec 2020 13:55:24
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'NY'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 13:55:09
User entered 'US'	System	17 Dec 2020 18:15:26

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '4'	System	11 Mar 2021 21:47:53
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '3'	System	11 Jan 2021 19:53:00
User entered '2'	System	23 Dec 2020 13:55:24
User entered '1'	System	17 Dec 2020 18:15:26

US3912163

Folder: SAE USA-US211-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:19:18

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:40:21
User entered '17/Dec/2020 18:15'	System	17 Dec 2020 18:15:26

US3912163

Folder: SAE USA-US211-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:19:18

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 13:55:09
User entered '1'	(b) (4), (b) (6)	17 Dec 2020 18:15:26

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'USA-US211-2020-MRNA-1273-P301000008'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'No (N)'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'No (N)'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'No (N)'	System	17 Dec 2020 18:14:10

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'No (N)'	System	17 Dec 2020 18:14:10

FDA-CBER-2022-1614-3511007

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'No (N)'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'No (N)'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'No (N)'	System	17 Dec 2020 18:14:10

Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18

Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:43:35
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	12 Mar 2021 19:13:20
Un-reviewed for Safety.	System	11 Mar 2021 21:47:53
DataPoint Un-verified.	System	11 Mar 2021 21:47:53
Signature has been broken.	System	11 Mar 2021 21:47:53
User entered 'Mark'	System	11 Mar 2021 21:47:53
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Un-reviewed for Safety.	System	23 Dec 2020 13:55:24
User entered 'Timothy'	System	23 Dec 2020 13:55:24
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'Mohammad'	System	17 Dec 2020 18:14:10

Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:43:37
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	12 Mar 2021 19:13:20
Un-reviewed for Safety.	System	11 Mar 2021 21:47:53
DataPoint Un-verified.	System	11 Mar 2021 21:47:53
Signature has been broken.	System	11 Mar 2021 21:47:53
User entered 'Hutchens'	System	11 Mar 2021 21:47:53
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Un-reviewed for Safety.	System	23 Dec 2020 13:55:24
User entered 'Vachris'	System	23 Dec 2020 13:55:24
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'Naqvi'	System	17 Dec 2020 18:14:10

FDA-CBER-2022-1614-3511012

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Un-reviewed for Safety.	System	23 Dec 2020 13:55:24
User entered empty.	System	23 Dec 2020 13:55:24
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'NY'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 13:55:09
User entered 'US'	System	17 Dec 2020 18:15:26

FDA-CBER-2022-1614-3511014

US3912163

Folder: SAE USA-US211-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:18

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '4'	System	11 Mar 2021 21:47:53
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '3'	System	11 Jan 2021 19:53:00
User entered '2'	System	23 Dec 2020 13:55:24
User entered '1'	System	17 Dec 2020 18:15:26

US3912163

Folder: SAE USA-US211-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:19:18

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:40:21
User entered '23/Dec/2020 13:55'	System	23 Dec 2020 13:55:24

US3912163

Folder: SAE USA-US211-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:19:18

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
User entered '1'	(b) (4), (b) (6)	23 Dec 2020 13:55:24

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'USA-US211-2020-MRNA-1273-P301000008'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'No (N)'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'No (N)'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'No (N)'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'No (N)'	System	17 Dec 2020 18:14:10

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'No (N)'	System	17 Dec 2020 18:14:10

FDA-CBER-2022-1614-3511023

US3912163

Folder: SAE USA-US211-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:18

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'No (N)'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'No (N)'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:43:35
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	12 Mar 2021 19:13:20
Un-reviewed for Safety.	System	11 Mar 2021 21:47:53
DataPoint Un-verified.	System	11 Mar 2021 21:47:53
Signature has been broken.	System	11 Mar 2021 21:47:53
User entered 'Mark'	System	11 Mar 2021 21:47:53
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Un-reviewed for Safety.	System	23 Dec 2020 13:55:24
User entered 'Timothy'	System	23 Dec 2020 13:55:24
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'Mohammad'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:43:37
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	12 Mar 2021 19:13:20
Un-reviewed for Safety.	System	11 Mar 2021 21:47:53
DataPoint Un-verified.	System	11 Mar 2021 21:47:53
Signature has been broken.	System	11 Mar 2021 21:47:53
User entered 'Hutchens'	System	11 Mar 2021 21:47:53
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Un-reviewed for Safety.	System	23 Dec 2020 13:55:24
User entered 'Vachris'	System	23 Dec 2020 13:55:24
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'Naqvi'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Un-reviewed for Safety.	System	23 Dec 2020 13:55:24
User entered empty.	System	23 Dec 2020 13:55:24
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'NY'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 13:55:09
User entered 'US'	System	17 Dec 2020 18:15:26

US3912163

Folder: SAE USA-US211-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:18

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '4'	System	11 Mar 2021 21:47:53
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '3'	System	11 Jan 2021 19:53:00
User entered '2'	System	23 Dec 2020 13:55:24
User entered '1'	System	17 Dec 2020 18:15:26

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form (3)
Generated On: 10 Jun 2021 10:19:18
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 16:11:01
User entered '11/Jan/2021 14:52'	System	11 Jan 2021 19:53:00

US3912163

Folder: SAE USA-US211-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:19:18

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 16:11:01
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:53:20
User entered '1'	(b) (4), (b) (6)	11 Jan 2021 19:53:00

US3912163

Folder: SAE USA-US211-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:18

SAEID

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'USA-US211-2020-MRNA-1273-P301000008'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'No (N)'	System	17 Dec 2020 18:14:10

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'No (N)'	System	17 Dec 2020 18:14:10

FDA-CBER-2022-1614-3511035

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'No (N)'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'No (N)'	System	17 Dec 2020 18:14:10

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'No (N)'	System	17 Dec 2020 18:14:10

FDA-CBER-2022-1614-3511038

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'No (N)'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'No (N)'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:43:35
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	12 Mar 2021 19:13:20
Un-reviewed for Safety.	System	11 Mar 2021 21:47:53
DataPoint Un-verified.	System	11 Mar 2021 21:47:53
Signature has been broken.	System	11 Mar 2021 21:47:53
User entered 'Mark'	System	11 Mar 2021 21:47:53
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Un-reviewed for Safety.	System	23 Dec 2020 13:55:24
User entered 'Timothy'	System	23 Dec 2020 13:55:24
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'Mohammad'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:43:37
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	12 Mar 2021 19:13:20
Un-reviewed for Safety.	System	11 Mar 2021 21:47:53
DataPoint Un-verified.	System	11 Mar 2021 21:47:53
Signature has been broken.	System	11 Mar 2021 21:47:53
User entered 'Hutchens'	System	11 Mar 2021 21:47:53
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Un-reviewed for Safety.	System	23 Dec 2020 13:55:24
User entered 'Vachris'	System	23 Dec 2020 13:55:24
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'Naqvi'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:40:21
Un-reviewed for Safety.	System	23 Dec 2020 13:55:24
User entered empty.	System	23 Dec 2020 13:55:24
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:15:19
User entered 'NY'	System	17 Dec 2020 18:14:10

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 13:55:09
User entered 'US'	System	17 Dec 2020 18:15:26

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '4'	System	11 Mar 2021 21:47:53
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '3'	System	11 Jan 2021 19:53:00
User entered '2'	System	23 Dec 2020 13:55:24
User entered '1'	System	17 Dec 2020 18:15:26

US3912163
Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form (4)
Generated On: 10 Jun 2021 10:19:18
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:43:41
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	12 Mar 2021 19:13:20
User entered '11/Mar/2021 13:47'	System	11 Mar 2021 21:47:53

Folder: SAE USA-US211-2020-MRNA-1273-P301000008
Form: Safety Report Form (4)
Generated On: 10 Jun 2021 10:19:18

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:43:41
User signature succeeded.	Mark Hutchens (b) (4)	12 Mar 2021 19:13:20
User entered '1'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:47:53

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'USA-US211-2021-MRNA-1273-P301000002'	System	05 Feb 2021 13:00:06

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'Yes (Y)'	System	05 Feb 2021 13:00:06

US3912163

Folder: SAE USA-US211-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:18

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'No (N)'	System	05 Feb 2021 13:00:06

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'Yes (Y)'	System	05 Feb 2021 13:00:06

US3912163

Folder: SAE USA-US211-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:18

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'Yes (Y)'	System	05 Feb 2021 13:00:06

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'No (N)'	System	05 Feb 2021 13:00:06

FDA-CBER-2022-1614-3511053

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'No (N)'	System	05 Feb 2021 13:00:06

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18

Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'No (N)'	System	05 Feb 2021 13:00:06

Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:53
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	12 Mar 2021 19:13:20
Un-reviewed for Safety.	System	11 Mar 2021 21:47:53
DataPoint Un-verified.	System	11 Mar 2021 21:47:53
Signature has been broken.	System	11 Mar 2021 21:47:53
User entered 'Mark'	System	11 Mar 2021 21:47:53
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'Timothy'	System	05 Feb 2021 13:00:06

FDA-CBER-2022-1614-3511056

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:55
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	12 Mar 2021 19:13:20
Un-reviewed for Safety.	System	11 Mar 2021 21:47:53
DataPoint Un-verified.	System	11 Mar 2021 21:47:53
Signature has been broken.	System	11 Mar 2021 21:47:53
User entered 'Hutchens'	System	11 Mar 2021 21:47:53
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'Vachris'	System	05 Feb 2021 13:00:06

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:11:47
User entered 'US'	System	05 Feb 2021 13:01:55

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '4'	System	12 Feb 2021 14:05:26
User entered '3'	System	11 Feb 2021 19:57:42
User entered '2'	System	08 Feb 2021 15:12:07
User entered '1'	System	05 Feb 2021 13:01:55

FDA-CBER-2022-1614-3511059

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'USA-US211-2021-MRNA-1273-P301000002'	System	05 Feb 2021 13:00:06

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'Yes (Y)'	System	05 Feb 2021 13:00:06

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'No (N)'	System	05 Feb 2021 13:00:06

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'Yes (Y)'	System	05 Feb 2021 13:00:06

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'Yes (Y)'	System	05 Feb 2021 13:00:06

FDA-CBER-2022-1614-3511064

Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'No (N)'	System	05 Feb 2021 13:00:06

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'No (N)'	System	05 Feb 2021 13:00:06

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'No (N)'	System	05 Feb 2021 13:00:06

Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:53
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	12 Mar 2021 19:13:20
Un-reviewed for Safety.	System	11 Mar 2021 21:47:53
DataPoint Un-verified.	System	11 Mar 2021 21:47:53
Signature has been broken.	System	11 Mar 2021 21:47:53
User entered 'Mark'	System	11 Mar 2021 21:47:53
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'Timothy'	System	05 Feb 2021 13:00:06

FDA-CBER-2022-1614-3511068

Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:55
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	12 Mar 2021 19:13:20
Un-reviewed for Safety.	System	11 Mar 2021 21:47:53
DataPoint Un-verified.	System	11 Mar 2021 21:47:53
Signature has been broken.	System	11 Mar 2021 21:47:53
User entered 'Hutchens'	System	11 Mar 2021 21:47:53
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'Vachris'	System	05 Feb 2021 13:00:06

FDA-CBER-2022-1614-3511069

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:11:47
User entered 'US'	System	05 Feb 2021 13:01:55

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '4'	System	12 Feb 2021 14:05:26
User entered '3'	System	11 Feb 2021 19:57:42
User entered '2'	System	08 Feb 2021 15:12:07
User entered '1'	System	05 Feb 2021 13:01:55

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
User entered '05/Feb/2021 08:01'	(b) (4) System	05 Feb 2021 13:01:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:11:47
User entered '1'	(b) (4), (b) (6)	05 Feb 2021 13:01:55

FDA-CBER-2022-1614-3511073

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'USA-US211-2021-MRNA-1273-P301000002'	System	05 Feb 2021 13:00:06

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'Yes (Y)'	System	05 Feb 2021 13:00:06

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'No (N)'	System	05 Feb 2021 13:00:06

FDA-CBER-2022-1614-3511076

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'Yes (Y)'	System	05 Feb 2021 13:00:06

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'Yes (Y)'	System	05 Feb 2021 13:00:06

FDA-CBER-2022-1614-3511078

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'No (N)'	System	05 Feb 2021 13:00:06

FDA-CBER-2022-1614-3511079

Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'No (N)'	System	05 Feb 2021 13:00:06

FDA-CBER-2022-1614-3511080

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'No (N)'	System	05 Feb 2021 13:00:06

Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:53
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	12 Mar 2021 19:13:20
Un-reviewed for Safety.	System	11 Mar 2021 21:47:53
DataPoint Un-verified.	System	11 Mar 2021 21:47:53
Signature has been broken.	System	11 Mar 2021 21:47:53
User entered 'Mark'	System	11 Mar 2021 21:47:53
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'Timothy'	System	05 Feb 2021 13:00:06

FDA-CBER-2022-1614-3511082

Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:55
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	12 Mar 2021 19:13:20
Un-reviewed for Safety.	System	11 Mar 2021 21:47:53
DataPoint Un-verified.	System	11 Mar 2021 21:47:53
Signature has been broken.	System	11 Mar 2021 21:47:53
User entered 'Hutchens'	System	11 Mar 2021 21:47:53
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'Vachris'	System	05 Feb 2021 13:00:06

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18

Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:11:47
User entered 'US'	System	05 Feb 2021 13:01:55

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '4'	System	12 Feb 2021 14:05:26
User entered '3'	System	11 Feb 2021 19:57:42
User entered '2'	System	08 Feb 2021 15:12:07
User entered '1'	System	05 Feb 2021 13:01:55

FDA-CBER-2022-1614-3511085

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form (2)
Generated On: 10 Jun 2021 10:19:18
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
User entered '08/Feb/2021 10:12'	(b) (4) System	08 Feb 2021 15:12:07

US3912163

Folder: SAE USA-US211-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:19:18

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:57:27
User entered '1'	(b) (4), (b) (6)	08 Feb 2021 15:12:07

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'USA-US211-2021-MRNA-1273-P301000002'	System	05 Feb 2021 13:00:06

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'Yes (Y)'	System	05 Feb 2021 13:00:06

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'No (N)'	System	05 Feb 2021 13:00:06

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'Yes (Y)'	System	05 Feb 2021 13:00:06

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'Yes (Y)'	System	05 Feb 2021 13:00:06

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'No (N)'	System	05 Feb 2021 13:00:06

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'No (N)'	System	05 Feb 2021 13:00:06

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'No (N)'	System	05 Feb 2021 13:00:06

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18

Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:53
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	12 Mar 2021 19:13:20
Un-reviewed for Safety.	System	11 Mar 2021 21:47:53
DataPoint Un-verified.	System	11 Mar 2021 21:47:53
Signature has been broken.	System	11 Mar 2021 21:47:53
User entered 'Mark'	System	11 Mar 2021 21:47:53
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'Timothy'	System	05 Feb 2021 13:00:06

Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:55
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	12 Mar 2021 19:13:20
Un-reviewed for Safety.	System	11 Mar 2021 21:47:53
DataPoint Un-verified.	System	11 Mar 2021 21:47:53
Signature has been broken.	System	11 Mar 2021 21:47:53
User entered 'Hutchens'	System	11 Mar 2021 21:47:53
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'Vachris'	System	05 Feb 2021 13:00:06

FDA-CBER-2022-1614-3511097

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18

Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:11:47
User entered 'US'	System	05 Feb 2021 13:01:55

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '4'	System	12 Feb 2021 14:05:26
User entered '3'	System	11 Feb 2021 19:57:42
User entered '2'	System	08 Feb 2021 15:12:07
User entered '1'	System	05 Feb 2021 13:01:55

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form (3)
Generated On: 10 Jun 2021 10:19:18
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '11/Feb/2021 14:57'	System	11 Feb 2021 19:57:42

US3912163

Folder: SAE USA-US211-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:19:18

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 14:05:06
User entered '1'	(b) (4), (b) (6)	11 Feb 2021 19:57:42

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'USA-US211-2021-MRNA-1273-P301000002'	System	05 Feb 2021 13:00:06

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'Yes (Y)'	System	05 Feb 2021 13:00:06

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'No (N)'	System	05 Feb 2021 13:00:06

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'Yes (Y)'	System	05 Feb 2021 13:00:06

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'Yes (Y)'	System	05 Feb 2021 13:00:06

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'No (N)'	System	05 Feb 2021 13:00:06

Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'No (N)'	System	05 Feb 2021 13:00:06

FDA-CBER-2022-1614-3511108

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'No (N)'	System	05 Feb 2021 13:00:06

Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:53
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	12 Mar 2021 19:13:20
Un-reviewed for Safety.	System	11 Mar 2021 21:47:53
DataPoint Un-verified.	System	11 Mar 2021 21:47:53
Signature has been broken.	System	11 Mar 2021 21:47:53
User entered 'Mark'	System	11 Mar 2021 21:47:53
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'Timothy'	System	05 Feb 2021 13:00:06

FDA-CBER-2022-1614-3511110

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:41:55
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	12 Mar 2021 19:13:20
Un-reviewed for Safety.	System	11 Mar 2021 21:47:53
DataPoint Un-verified.	System	11 Mar 2021 21:47:53
Signature has been broken.	System	11 Mar 2021 21:47:53
User entered 'Hutchens'	System	11 Mar 2021 21:47:53
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:00:51
User entered 'Vachris'	System	05 Feb 2021 13:00:06

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 10:19:18
Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:11:47
User entered 'US'	System	05 Feb 2021 13:01:55

US3912163

Folder: SAE USA-US211-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:19:18

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:47:43
User entered '4'	System	12 Feb 2021 14:05:26
User entered '3'	System	11 Feb 2021 19:57:42
User entered '2'	System	08 Feb 2021 15:12:07
User entered '1'	System	05 Feb 2021 13:01:55

US3912163
Folder: SAE USA-US211-2021-MRNA-1273-P301000002
Form: Safety Report Form (4)
Generated On: 10 Jun 2021 10:19:18
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
User entered '12/Feb/2021 09:05'	(b) (4) System	12 Feb 2021 14:05:26

US3912163

Folder: SAE USA-US211-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:19:18

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:59:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:47:43
User entered '1'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 14:05:26